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No.

In The

Supreme Court of the United States

October Term, 1999

JOHN HANLON AND RUTH ANN HANLON, PARENTS AND NEXT FRIENDS OF MICHAEL HANLON, and MARK PLAVIN AND TONY REISS-PLAVIN, PARENTS AND NEXT FRIENDS OF RACHEL PLAVIN,

Petitioners,

-vs.-

DONNA E. SHALALA, SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

APPENDICES TO PETITION FOR A WRIT OF CERTIORARI

RICHARD GAGE
Attorney for Petitioners
Gage & Moxley
623 West 20th Street
P.O. BOX 1223
Cheyenne, WY 82003-1223
(307) 632-1112

APPENDICES

APPENDIX A: DECISION OF THE OFFICE OF SPECIAL MASTERS IN AND FOR THE UNITED STATES COURT OF FEDERAL CLAIMS, DATED MAY 31, 1994

UNPUBLISHED
In the United States Court of Federal Claims
OFFICE OF THE SPECIAL MASTERS
No. 90-1334V
May 31, 1994

JOHN HANLON AND RUTH ANN HANLON, PARENTS AND NEXT FRIENDS OF MICHAEL HANLON,

Petitioners,

vs.

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Respondent.

Richard Gage, Cheyenne, WY, for petitioners.
Mary Hampton Mason, Washington, DC, for respondent.

DECISION

MILLMAN, Special Master

On behalf of Michael Hanlon (hereinafter, "Michael"), petitioners filed a petition on September 25, 1990 for compensation under the National Childhood Vaccine Injury Act

of 1986[1] (hereinafter, the "Vaccine Act" or the "Act").

Petitioners have satisfied the jurisdictional prerequisites provided in § 300aa-ll(c) of the Act by showing that Michael has not previously collected an award or settlement of a civil action for damages arising from the vaccine injury, that they have incurred $1,000 in unreimbursable medical expenses, and that the DPT vaccination was administered to Michael in the United States.

Petitioners allege that Michael suffered significant aggravation of his pre-existinq tuberous sclerosis (TS) in the form of a residual seizure disorder within the Table time limits of the Act. 42 U.S.C. § 300aa-14(a)(D) and (E). Respondent defends with the assertion that the onset of Michael's seizure disorder occurred outside the Table time limits. In the alternative, respondent claims that Michael's seizure disorder was caused by a factor unrelated: TS. 42 U.S.C. § 300aa-13(a) (1) (B).

Two hearings were held: October 21, 1991 (at the Mayo Clinic) and May 6, 1994. Testifying for petitioners were Dr. Manuel Gomez at the Mayo Clinic, Ruth Ann Hanlon, Patricia Ditto, Ruth Leahy, and John Hanlon. Because of the superfluity of medical testimony already amassed in TS cases before this Special Master, and the pivotal question of whether indeed Michael's seizures began within three days of his DPT vaccination, the local hearing was restricted to lay testimony. Petitioners filed reports from their expert, Dr. Marcel Kinsbourne. Respondent filed an expert report from Dr. Russell D. Snyder, who stated that the onset of Michael's seizure disorder did not occur on-Table and that Michael's TS was not significantly aggravated by DPT vaccine.

FACTS

Michael was born on March 30, 1978. He received his

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[1]The statutory provisions governing the Vaccine Act are found in 42 U.S.C.A. § 300aa—l et seq. (West 1991). The National Vaccine Injury Compensation Program comprises Part 2 of the Vaccine Act. For convenience, further reference will be to the relevant subsection of 42 U.S.C. § 300aa.

first DPT vaccination on June 1, 1978 when he was two months old. Med. Recs. at 15. Petitioner alleges he suffered his first seizure one day later.

Michael received his second DPT vaccination on July 28, 1978 when he was four months old. On examination, Dr. Jackson Erffmeyer noted that Michael was doing well. Med. Recs. at 15.

Michael received his third DPT vaccination on October 3, 1978 when he was six months old. On examination, Dr. Erffmeyer noted that he had tic-like movements of his head and neck and questioned whether he was doing well. Med. Recs. at 15. On November 2, 1978, Dr. Erffmeyer noted that Michael had fewer tics. Med. Recs. at 17.

On December 28, 1978, Dr. Erffmeyer noted that Michael had had more tics the prior week and was planning to see a neurologist, Dr. Gaylord Bennett, that week. Med. Recs. at 17.

Michael saw Dr. Bennett on January 17, 1979. The history he recorded indicates that between the ages of two and four months, Michael had repetitive eye blinking occasionally. Between the ages of four and six months, he had recurrent blinking of the eyes associated with some jerking of the head to the right. These episodes were unaccompanied by fever. Med. Recs. at 22-23.

From March 26, 1979 to March 27, 1979, Michael was a patient at St. Francis Hospital. The history recorded indicates that at two months, Michael experienced blinking spells that later developed into four to ten nodding spells daily. Occasionally, Michael exhibited an exaggerated head jerk and lost his balance. Med. Recs. at 26.

Michael received his fourth DPT vaccination on October 1, 1979. Med. Recs. at 17. Thereafter, he suffered four seizures daily. He was rehospitalized at St. Francis from July 1, 1980 to July 2, 1980. The history recorded indicates that the onset of his seizure disorder occurred at two months of age. Med. Recs. at 29.

TESTIMONY

Dr. Manuel Gomez, the world's expert in TS, testified on October 21, 1991. Dr. Gomez's testimony on TS was taken at the

Mayo Clinic and is described in Costa v. Secretary of HHS, No. 90-1476V, slip op. at 10-17 (Cl. Ct. Spec. Mstr. Feb. 26, 1992). (A description of Dr. Gomez's textbook and article on TS is on pp. 5-0 of the same opinion.)

Dr. Gomez testified that TS is not an encephalopathy. Gomez Tr. at 99. Rather, TS is a genetic disorder which is either inherited or results from a mutation. Gomez Tr. at 96. Brain growth controls tuber growth. Tubers exist at birth and do not multiply. Gomez Tr. at 97. The most common presenting symptom in TS is seizures. Gomez Tr. at 100. There is a demonstrable correlation between the presence of many low attenuated lesions and the frequency and severity of seizures and mental retardation in an infant less than one year old. Gomez Tr. at 101.

The most common age for an onset of seizures in TS children is the first year of life. The most symptom of presentation is infantile spasms. Infantile spasms are age-dependent seizures
occurring between ages of three and eight months, regardless of the cause. Gomez Tr. at 103.

DISCUSSION

The court ruled from the bench for petitioners. The attached pages recount the testimony as well as the court's reasoning.

CONCLUSION

Petitioners are entitled to a Program award in an amount yet to be determined. The court hopes that the parties will be able to settle the damages portion of this case without a hearing, and suggests petitioners and respondent retain a joint Life Care Planner and file a Life Care Plan expeditiously. The court will hold a telephone conference soon to see how the parties are progressing in resolving the damages issue.

IT IS SO ORDERED.

DATED May 31, 1994

s/
Laura D. Millman
Special Master

Bench Ruling by Special Master Laura Millman

No. 901334V April 6, 1994

THE COURT: It's not often that I rule on the record but I seem to be doing it more often lately and I feel comfortable doing it now.

As you know, I have all of the tuberous sclerosis cases and so I've become an expert, somewhat, in the medical records pertaining to T.S. and I read medical records in every other case, as well. And as you know, as well, when there's a conflict between what the parents are saying happened and the medical records it immediately raises red flags as to what is really true and the parents are perhaps less believable. But I don't see a remarkable difference, if any difference at
all, between what the parents are saying here and what is in the medical records.

I would not be surprised if they didn't relate the DPT shots to the tics because they didn't see a child that was feverish, uncomfortable, screaming, in pain. They see a placid child, who's still the same child they know and he has a few eye tics. If you go into the subway you'll probably see people with eye tics. It happens every day. you don't necessarily attribute something serious to this condition, although, obviously when it recurred and got worse with more symptoms, they became more alarmed.

And that's manifested in the medical records too. The pediatrician's first note as a question mark, tic like movements, head and neck. And that of course precedes the third DPT.

The medical records are not so precise that you could say we don't need the testimony of the Petitioners as was in the Costa case, where it was blatantly there. Everything in the medical records -- you didn't have to hear from Mr. and Mrs. Costa. But having heard from them, I find them believable, particularly, Mrs. Hanlon, who has an excellent memory. I am not surprised that she

would remember certain events, and gauge them toward the fact that they had seen the doctor the day before these things and now what is this. It's a close family. She's got matriarchy, I think you referred to, Mr. Gage. supporting her, people visiting her every day. Apparently the women are a little more precise than the men, which is not surprising. And, you know, it's all consistent. There's nothing whatever to raise in my mind a lack of credibility. There's nothing to raise in my mind that doctors were told something which now the parents are saying did or didn't happen. Dr. Bennett is the first professional who is geared toward examining this type of thing. The -- I'll never pronounce this man's name -- the pediatrician who -- I've got it -- I just want to find it --Dr. Erffmeyer, who is a
pediatrician, obviously was not sure what this was and responsibly referred them to Dr. Bennett. Dr. Bennett has always diagnosed these tics as seizures.

We know from other T.S. cases, where there are tics or twitches, or whatever, that T.S. can begin in a rather subtle way. You don't know what you're looking at. It could be benign. And unfortunately, due to the nature of the illness, they become more severe, more repetitive. Whether or not the statement in the affidavits of the increasing refers to number or duration of the seizure or type of symptomatology doesn't really impress me because the initial time of the seizures was obviously on table.

I have no reason to doubt, not only Mr. and Mrs. Hanlon, but Mrs. Ditto, as well as the grandmother, Mrs. Leahy, that at the time of the reception for Mrs. Hanlon's brother's wedding, there was this collection of ladies, all gathered around there looking at this little baby. They would have looked at him even if he wasn't twitching. But he was twitching . And they said it will go away, which you want to believe. You don't want to look at a child and say ah ha, this is a very serious neurologic illness. Take this child to the doctor at once. No, it's going to go away. And it did. And it came back.

We know from numerous discussions that the program does benefit the Petitioners if they show an on-table onset

ofseizure activity, particularly in a T.S. child. We know from the Suel case that one seizure equals significant aggravation, that is a judicial mandate as far as I'm concerned, coming from Judge Merow in the Suel case and a dictum coming from Judge Tidwell in the Costa case.

It may not be applicable in non-T.S. cases but it certainly seems to be applicable in T.S. cases.

I don't think from hearing Mr. Hanlon that the child is as severe as some T.S. children, severely injured, as some T.S. children and I would hope that to speed things along we could do damages without life care plans but I would leave that up to the counsel to see what they need because the child is attending school although receiving special education and is on seizure medication and still seizing. It is a pre-Act case so of course compensation is limited to what the statute permits.

I find that the child, Michael Hanlon's seizures began within table time of his first DPT shot, administered June 1, 1978 and that his seizures have continued past six months. That those seizures significantly aggravated his underlying T.S. so that whereas prior to the DPT he had no seizures, subsequent to the DPT he did and continues to have them to this day.

APPENDIX B: DECISION OF THE OFFICE OF SPECIAL MASTERS IN AND FOR THE UNITED STATES COURT OF FEDERAL CLAIMS DATED DECEMBER 29, 1994

UNPUBLISHED
In the United States Court of Federal Claims
OFFICE OF THE SPECIAL MASTERS
No. 91-1555V
December 29, 1994

MARC PLAVIN and TONI REISS, Parents and Next Friends of RACHEL LEAH REISS-PLAVIN,

Petitioners,

vs.

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Respondent.

Richard Gage, Cheyenne, WY, for petitioners.
Richard A. Schollmann, Washington, DC, for respondent.

DECISION

MILLMAN, Special Master

On behalf of Rachel Leah Reiss-Plavin (hereinafter, "Rachel"), petitioners filed a petition on October 20, 1990 for compensation under the National Childhood Vaccine Injury Act of 1986[2] (hereinafter, the "Vaccine Act" or the "Act") Petitioners have satisfied the jurisdictional prerequisites provided in § 300aa-

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[2]The statutory provisions governing the Vaccine Act are found in 42 U.S.C.A. § 300aa-l et seg. (West 1991). The National Vaccine Injury Compensation Program comprises Part 2 of the Vaccine Act. For convenience, further reference will be to the relevant subsection of 42 U.S.C. § 300aa.

11(c) of the Act by showing that Rachel has not previously collected an award or settlement of a civil action for damages arising from the vaccine injury, that they have incurred $1,000 in unreimbursable medical expenses, and that the DPT vaccination was administered to Rachel in the United States.

Petitioners allege that Rachel suffered significant aggravation of her pre-existing tuberous sclerosis (TS) in the form of a residual seizure disorder (RSD) within the Table time limits of the Act. 42 U.S.C. § 300aa-l4 (a) (I) (D) and (B) Respondent defends with the assertion that the onset of Rachel's seizure disorder occurred outside the Table time limits. In the alternative, respondent claims that Rachel's seizure disorder was caused by a factor unrelated: TS. 42 U.S.C. § 300aa-13 (a) (1) (B)

No hearing was held in the instant matter because the records are sufficient for the court to reach a determination on entitlement. However, preliminary testimony was taken on October 21, 1991 at the Mayo Clinic from Dr. Manuel Gomez on the nature of TS, and the effect of DPT vaccine on TS children. Petitioners filed the expert report of Dr. Marcel Kinsbourne, a pediatric neurologist.

FACTS

Rachel was born on June 8, 1989. She received her first DPT vaccination on August 4, 1989 at the age of two months. She received her second DPT vaccination on September 15, 1989, when she was three and a half months. Med. Recs. at 45. The parents allege that, later that day, she was staring, her left arm shook, and she drew her legs up.

On September 26, 1989, Rachel was brought to Humana Hospital. Dr. Jacqueline Campbell took the history that Rachel had been healthy until her mother noticed occasional trembling of her left hand while she nursed and one blank stare. No date is given for the onset. She did not have a reaction to her second DPT ten days earlier. Med. Recs. at 49.

On November 29, 1989, Dr. Baumann at the University of Kentucky Outpatient Clinic took a history of onset at approximately two months with a shaking left hand. By two and

a half months, these were apparently seizures. Med. Recs. at 132.On December 12, 1989, Drs. Ryan and Hall recorded that the first seizure occurred on September 15, 1989 following a DPT vaccination. While nursing, Rachel pulled away from the nipple, and her left arm vibrated. She began shaking and staring. Med. Recs. at 147.

A history given at the University of Kentucky Medical Center on November 1, 1990 states an onset of seizures at three and a half months. Med. Recs. at 156.

A letter dated March 15, 1991 from Dr. Jacqueline Campbell states that Rachel's mother called her on September 15, 1989 to discuss Rachel's fussiness, apparent abdominal cramping, and occasional brief arm tremor. Med. Recs. at 289.

TESTIMONY

Dr. Manuel Gomez, the world's expert in TS, testified on October 21, 1991. Dr. Gomez's testimony on TS was taken at the Mayo Clinic and is described in Costa v. Secretary of HHS, No. 90-1476V, slip op. at 10-17 (Cl. Ct. Spec. Mstr. Feb. 26, 1992) (A description of Dr. Gomez's textbook and article on TS is on pp. 5-10 of the same opinion.)

Dr. Gomez testified that TS is not an encephalopathy. Gomez Tr. at 99. Rather, TS is a genetic disorder which is either inherited or results from a mutation. Gomez Tr. at 96. Brain growth controls tuber growth. Tubers exist at birth and do not multiply. Gomez Tr. at 97. The most common presenting symptom in TS is seizures. Gomez Tr. at 100. There is a demonstrable correlation between the presence of many low attenuated lesions and the frequency and severity of seizures and mental retardation in an infant less than one year old. Gomez Tr. at 101.

The most common age for an onset of seizures in TS children is the first year of life. The most common symptom of presentation is infantile spasms. Infantile spasms are age-dependent seizures occurring between the ages of three and eight months, regardless of the cause. Gomez Tr. at 103.

Dr. Gomez stated, "The timing is very important. You

don't want to provoke or bring on the seizure. If there is any way to prevent that, you should try to prevent it." Gomez tr. at 48-49. Dr. Gomez has never recommended giving pertussis vaccine to any child he knows has TS. Gomez. tr. at 48.

Dr. Kinsbourne states in his report that Rachel's onset of symptoms was the same day as the second DPT vaccination. She was admitted to the hospital eleven days later. Dr. Kinsbourne diagnosed encephalopathy leading to seizures and cognitive deficits.

Counsel took the deposition of Dr. Jacqueline Campbell, Rachel's pediatrician. She recounted that Rachel's mother called her on September 15, 1989, the evening of the DPT vaccination she had administered. Campbell tr. at 2; Ps' Ex. 6; Med. Recs. at 289. Rachel's mother complained that Rachel was cramping and had an occasional hand tremor. Campbell tr. at 4.

Dr. Campbell stated that when she put "no reaction" in the Humana Hospital records pertaining to Rachel after her second DPT vaccination. she meant that Rachel did not have the usual reaction of high fever, high pitched cry, and severe irritability. Campbell tr. at 6.

Dr. Campbell stated one does not make a diagnosis until one have evaluated everything. In retrospect, "these tremors that ... the mother had mentioned in the past . . . were probably very minor seizures. We did not appreciate that until this episode happened and the story became much more clear." Campbell tr. at
6-7.

Dr. Campbell also stated that the hand tremors to which Rachel's mother referred in the phone call of September 15, 1989 were probably minor seizure activity. Campbell tr. at 7.

Petitioners submitted affidavits of fact witnesses to attest to Rachel's seizures beginning within three days of her DPT vaccination: Lauri Vinick, Allison Brown-Rice, and Sandra L. Hough. Petitioners' initial and supplemental affidavits are consistent with on-Table onset.

DISCUSSION

The records and Dr. Campbell's testimony clearly support a finding that Rachel's seizures began on-Table after her second DPT vaccination. The earliest medical record at Humana is ambivalent. But Dr. Campbell recorded that history and subsequently clarified what she meant by writing "no reaction" to the second DPT, i.e., she was looking for fever and inconsolable crying. In addition, Dr. Campbell testified that Rachel's mother called her the evening of the second DPT vaccination to report what Dr. Campbell later agrees are seizures. Subsequent medical histories just a few months later are consistent with on-Table onset as are the affidavits of individuals who were in contact with petitioners at the time.

Petitioners have prevailed in satisfying their burden of showing Rachel having an on-Table onset of seizures which constituted a significant aggravation of her TS.

CONCLUSION

Petitioners are entitled to a Program award in an amount yet to be determined. The court hopes that the parties will be able to settle the damages portion of this case without a hearing, and suggests petitioners and respondent retain a joint Life Care Planner and file a Life Care Plan expeditiously. The court will hold a telephone conference soon to see how the parties are progressing in resolving the damages issue.

IT IS SO ORDERED.

DATED: December 29, 1994

s/
Laura D. Millman
Special Master

APPENDIX C: "TS OMNIBUS DECISION" OF THE OFFICE OF THE SPECIAL MASTERS OF THE UNITED STATES COURT OF FEDERAL CLAIMS, DATED SEPTEMBER 15, 1997

1997 WL 602115 (Fed. Cl. Spec. Mstr.)

OFFICE OF SPECIAL MASTERS
PUBLISHED

Barnes 92-0032V
Barnes 90-1IO1V
Bradbary 90-2770V
Copeland 90-0867V
Decker 90-11 ISV
Decker 90-11 16V
Flanagan 90-1 126V
Gallagher 95-0191 V
Hanlon 90-1334V
Henkel 90-3314V
Hulbert 90-1335V
Johnson 90-311 OV
Kouba 90-3524V
Langford 91-0521V
Loney 90-0926V
Miller 90-2764V
Moody 91-0393V
Muller 90-2724V
Plavin 91-1555V
Schueler 91-0124V
Turner 90-3409V
Ulicny 95-0189V

Robert Moxley and Richard Gage,[1] Cheyenne, WY, for petitioners.
Karen P. Hewitt and Mary H. Mason, Washington, DC, for respondent.

TS OMNIBUS DECISION

MILLMAN, Special Master

Statement of the Case

The above-captioned cases all deal with a disease called tuberous sclerosis ("TS") and were filed under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-1 et seq (West 1991 & Supp. 1996) ("Vaccine Act"). Initially, other special masters and the undersigned heard and decided the TS cases individually. Subsequently, all the TS cases were transferred to the
undersigned for disposition. As part of determining the common issues in these cases, in an analogy to 28 U.S.C. §1407 (multidistrict litigation), the undersigned held an Omnibus Hearing in two parts: October 8-11, 1996 and June 3-4, 1997.

The following TS cases were decided prior to consolidation before the undersigned: Wilson v. Secretary. HHS,

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[1] Mssrs. Moxley and Gage do not represent all the petitioners in the caption. However, those attorneys who do represent non-Moxley/Gage petitioners agreed to the Omnibus Proceedings with Mssrs. Moxley and Gage, who have the overwhelming number of cases and considerable experience in the area of TS, representing all petitioners. The undersigned, in each order she issued, afforded non-Moxley/Gage counsel the opportunity to provide different evidence or approaches than Mssrs. Moxley and Gage. None of the other attorneys chose to diverge from Mssrs. Moxley and Gage. If, in the future, other petitioners' counsel have different evidence on the common issues the court evaluated at the Omnibus Hearing, the undersigned will certainly receive it. It would be hard, however, to perceive how any more evidence could be available, considering the six days of exhaustive testimony the court has heard on the common issues.

No. 89-65V, 1991 WL 20064 (Cl. Ct. Spec. Mstr. Jan. 22, 1991) (petitioners entitled to damages for on-Table residual seizure disorder [RSD]); Huber v. Secretary. HHS, 89-72V (Cl. Ct. Spec. Mstr. Aug. 6, 1990; Apr. 5, 1991) (petitioners entitled to damages; respondent did not present a defense); Murphy v. Secretary. HHS No. 90-882V (Cl. Ct. Spec. Mstr. Apr. 25, 1991) (petitioners' testimony conflicted with the contemporaneous medical records; petition dismissed); Copeland v. Secretary. HHS, No. 90-867V, 1993 WL 12894 (Fed. Cl. Spec. Mstr. Jan. 7, 1993) (DPTsignificantly aggravated TS; damages pending and reassigned to the undersigned special master).

On October 21, 1991, the undersigned heard the testimony of Dr. Manuel Gomez, the world's expert on TS, at the Mayo Clinic, Rochester, MN. The intent of the undersigned was to apply Dr. Gomez's testimony to all TS cases. The first TS case that the undersigned decided was Costa v. Secretary. HHS, No. 90-1476V, 1992 WL 47334 (Cl. Ct. Spec. Mstr. Feb. 26, 1992), vacated and remanded, 26 Cl. Ct. 866 (1992), on remand, 1992 WL 365421 (Fed. Cl. Spec. Mstr. Nov. 5, 1992). In Costa this court held that petitioners were entitled to an award of damages based on their proof of an on-Table RSD.

Upon motion of respondent, this special master certified the case for interlocutory appeal and respondent then filed a Motion for Review on the issue of whether the undersigned erred in analyzing the case as an on-Table RSD, rather than as an on-Table significant aggravation.

The U.S. Claims Court (now the U.S. Court of Federal Claims), per the Honorable Moody R. Tidwell, held that respondent's analysis was correct, and that petitioners were entitled to damages because the DPT did significantly aggravate the vaccinee's TS. Id. at 871. The appellate court also held that TS was a latent RSD and a latent encephalopathy. Id. Since Stephen Costa did not have any seizures before he received his DPT vaccination, and did seize within Table time after he received DPT, the DPT significantly aggravated his TS. Id.

The undersigned evaluated the remaining TS cases solely

under a theory of significant aggravation. The next case this court decided was Suel v. Secretary. HHS, No. 90-935V, 1993 WL 241430 (Fed. Cl. Spec. Mstr. June 18, 1993), rev'd and remanded, 31 Fed. Cl. 1(1993). The undersigned held that David Suel's eyes rolling back two days after his DPT vaccination, although a seizure, was not of sufficient severity as to constitute a substantial deterioration under the definition of "significant aggravation" in the statute at 42 U.S.C. §300aa-33. The U.S. Court of Federal Claims, per the Honorable James F. Merow, reversed and remanded, holding that a single seizure in a previously asymptomatic child was per se significant aggravation of his TS.

In two other TS cases, Moon v. Secretary. HHS, No. 90-2495 (1994) (injury case), and Perkins v. Secretary. HHS, No. 90-2141 (1995) (death case), the parties settled before the undersigned determined entitlement. Costa, supra, also settled damages after the decision on remand. Respondent did not further appeal Costa.

In 1995, respondent asserted that it had additional evidence previously unavailable which proves epidemiologically (and is confirmed neurologically) that if a vaccinee has eight or more tubers, he or she will inevitably develop seizures and become moderately or severely mentally retarded. Respondent offers as its basis an epidemiological meta-analysis of studies of TS. In the hope of facilitating the disposition of all remaining TS cases and any subsequent tag-along cases of TS,[2] the undersigned held an Omnibus Hearing on October 8-11, 1996 to hear respondent's new evidence. At that part of the hearing, respondent submitted an abstract of a study ("the Jozwiak study") which had not yet been written. The undersigned continued the hearing until it would receive the completed Jozwiak study plus

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[2]There is dictum to the effect that applying the decision of an Omnibus Hearing to a tag-along case is inherently unfair. Johnson v. Secretary, HHS, 33 Fed. Cl. 712, 730 n.10 (Ct. Cl.1996), aff'd, 99 F.3d 1160 (1996). However, in the federal district courts' usage of multidistrict litigation, the applicability of a decision on common issues to tag-along cases is part of the raison d'être of the proceeding.

other materials that were still outstanding.

Subsequently, the other materials were provided and respondent filed the Jozwiak study[3], an independent analysis of 106 TS children in Poland. The authors of the study conclude that receipt of DPT did not affect the onset of seizures in TS children. Jozwiak, May 13, 1997 draft at 13. The most important determinant of severity of mental retardation was whether or not the TS individual had infantile spasms. Id. at 14. Jozwiak, by controlling for infantile spasms (an age-related seizure disorder whose occurrence falls generally between the ages of three and eight months) as a variable, also concluded that the age of onset of seizures did not affect the severity of mental retardation in a TS child. Id. The court heard testimony on this evidence on June 3-4, 1997.

Recently, the U.S. Supreme Court decided two cases that are pertinent to the issues at hand: Daubert v. Merrell-Dow Pharmaceuticals. Inc., 509 U.S. 579 (1993) (re: scientific evidence admissibility with an extensive discourse of the nature of valid scientific testimony) and Whitecotton v. Secretary, HHS, 514 U.S. 268 (1995) (discussing onset), on remand, 81 F.3d 1099 (Fed. Cir. 1996) (discussing the criteria for proving significant aggravation under the Vaccine Program). In essence, the Federal Circuit asked if the vaccinee's current condition was worse than his or her pre-vaccination condition and, secondly, if the significant worsening began within Table time of the vaccination. 81 F.3d at 1107. If the answer to these two questions is in the affirmative, the burden passes to respondent to prove by a causation in fact standard that the pre-existing illness, not the vaccination, caused the significant worsening. Id.

By trying common issues together, including respondent's extensive meta-analysis of epidemiological studies of TS, the

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[3]Jozwiak, S. et al., "Poor Mental Development in TSC Patients: Clinical Risk Factors," drafts dated February 12, 1997 and May 13, 1977. Hanlon, R. Exs. BBB, EEE. (All references to exhibit numbers will come from the Hanlon case.)

undersigned hopes to facilitate the disposition of over twenty cases (even those in which entitlement had already been decided but which were awaiting disposition of damages).

TESTIMONY

Dr. Manuel Gomez, the world's expert in TS, testified on October 21, 1991 as part of all TS cases. Dr. Gomez's testimony on TS was taken at the Mayo Clinic and is described in Costa v. Secretary, HHS, No. 90-1476V, 1992 WL 47334, *5-*8 (Cl. Ct. Spec. Mstr. Feb. 26, 1992), vacated and remanded, 26 Cl. Ct. 866 (1992), on remand, 1992 WL 365421 (Fed. Cl. Spec. Mstr. Nov. 5, 1992). Dr. Gomez, at the time of the taking of his initial testimony, was a pediatric neurologist at the Mayo Clinic, Rochester, MN. He was also a member of the Medical Advisory Board and Research Committee of the National Tuberous Sclerosis Association.[4] R. Ex. 111. He has edited Tuberous Sclerosis (Raven Press, 1979; 2d ed., 1988; a third edition is forthcoming) (P. Ex. 56; R Ex. C). He authored "Tuberous Sclerosis Complex in Olmsted County, Minnesota, 1950-89," 48 Arch Neur 400-0 1 (April 1991) (R. Ex. E); "Tuberous sclerosis, early onset of seizures, and mental subnormality: Study of discordant [mono]zygous twins," 32 Neur 604-11 (1982) (P. Ex. 57). As of the date of his initial testimony, Dr. Gomez had authored 151 publications. Gomez Tr. at 6. Dr. Gomez's textbook on TS and his article about twins are described in the first opinion in Costa.

Dr. Gomez had been practicing pediatric neurology for thirty-one years at the time of his initial testimony. Gomez Tr. at 8. He has seen 150 out of the 380 TS patients the Mayo Clinic has had. The Mayo Clinic has more TS cases than any other institution. Gomez Tr. at 9.

Dr. Gomez testified that TS is not an encephalopathy. Gomez Tr. at 99. Rather, TS is a genetic disorder which is either

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[4]Currently, Dr. Gomez is Emeritus Professor of Pediatric Neurology, Senior Consultant in Pediatric Neurology at the Mayo Clinic

inherited or results from a mutation. Gomez Tr. at 96. Brain growth controls tuber growth. Tubers exist at birth and do not multiply. Gomez Tr. at 97. The most common presenting symptom of TS is seizures. Gomez Tr. at 100. There is a demonstrable correlation between the presence of many low attenuated lesions and the frequency and severity of seizures and mental retardation in an infant less than one year old. Gomez Tr. at 101.

The most common age for an onset of seizures in TS children is the first year of life. The most common symptom of presentation is infantile spasms. Infantile spasms are age-dependent seizures occurring between the ages of three and eight months, regardless of the cause. Gomez Tr. at 103.

The TS lesions or tubers are located on the cortex and, depending on their location, one would expect seizures characteristic of the function of that brain area. Thus, if there is a tuber in the motor area of the brain, one would expect a motor seizure in the upper side of the brain. If the tuber is in the occipital area, one would expect a more sensory seizure. There are certain parts of the brain where a lesion is more likely to produce seizures, i.e., the temporal lobes (as compared to the frontal lobes). Gomez Tr. at 19.

When an individual has more than five lesions detectable on MRI in the brain, most likely he or she will have seizures. We do not see all the lesions. If we detect five, there are probably twice as many. Gomez Tr. at 20. If an infant has extensive, numerous lesions, he will probably have lots of seizures and also be mentally retarded. Gomez Tr. at 32-33.

One of every 14,000 people has TS. Gomez Tr. at 22. We do not know what percentage of people with TS will be mentally retarded because we do not know how many people there are with TS in the general population. Of the people coming to the Mayo Clinic with TS (a biased population), 45 percent are mentally retarded. Parents of children with TS may have TS themselves and lead a normal life. Gomez Tr. at 23.

The 45 percent includes both the patients and their dependents. In 1966 or 1967, to Dr. Gomez's great surprise, he found that many TS cases were not mentally retarded as the books said they should be. Probably one-third of them were normal with normal intelligence. Gomez Tr. at 10. Dr. Gomez opined that the incidence of mental retardation outside the Mayo patient population is much lower than 45 percent. Gomez Tr. at 26. He believes that Dr. John Osborne's statement in his paper "Epidemiology of Tuberous Sclerosis" (615 Annals of the New York Academy of Science, 125-27 (April 1991); P. Ex. 55), that a true frequency of mental retardation in TS is approximately 33 percent is a good statement. Gomez Tr. at 91. If we could find everyone with TS, Dr. Gomez believes that the incidence of mental retardation should be much lower than what he estimated (45 percent) and perhaps even lower than what Dr. Osborne estimated (33 percent). Gomez Tr. at 92. Dr. Gomez testified that the true incidence of mental normalcy in TS people could even be higher than 67 percent. He stated that as more people who are clinically normal are examined and are discovered to have TS, the incidence of mental retardation keeps declining. Gomez Tr. at 93.

Dr. Gomez testified that the purpose of his writing the paper in the journal, Neurology (P. Ex. 57), on the two sets of twins was to indicate that seizures influence the outcome of the disorder. Gomez Tr. at 29. Repetitive seizures do lasting brain damage to infants. Gomez Tr. at 3 5-36. Infantile spasms are a form of epilepsy. Gomez Tr. at 43: Infantile spasms tend to come in clusters (ten, fifteen, or even one hundred). These children are either severely retarded to begin with because of severe pathology, or if they are not, they are going to be. Onset at the age of five, six, or seven months is very damaging, more so than if infantile spasms occurred later on. Infantile spasms rarely begin after the age of one year. Gomez Tr. at 44.

Dr. Gomez testified that the incidence of complication of DPT vaccination is 1 in 300,000. Gomez Tr. at 47. The chance of both twins in a set having a seizure reaction is 1 in 90,000,000.

Gomez Tr. at 47. Dr. Gomez stated that it is a good precaution not to give anybody who has TS any chance of developing seizures. Thus, he has never recommended giving pertussis medication to a child that he knows has TS: "It is better not to take any chance." Gomez Tr. at 48. Pertussis immunization has frequently been cited as a triggering factor or a cause of infantile spasms. Dr. Gomez differentiated between triggering factor and cause by stating, "I think trigger is the easy way out. Triggering is credible; causing is hard to prove." Gomez Tr. at 83.

The most common presenting symptom of TS is seizures. Gomez Tr. at 100. The incidence of seizures is much higher in the first year of life in TS than at any other time. Dr. Gomez testified, "The timing is very important. You don't want to provoke or bring on the seizure. If there is any way to prevent that, you should try to prevent it." Gomez Tr. at 4849.

When questioned by the court regarding how to choose between TS and DPT vaccine as the cause of the seizures, Dr. Gomez stated that it is clearly by the chronology of events. The peak onset related to the DPT shot would be within 24, 48, or 72 hours after the shot and not much more after that. Gomez Tr. at 121. After 72 hours, Dr. Gomez would probably relate a seizure in a TS patient to the TS rather than to a DPT inoculation. Gomez Tr. at 122.

Dr. Gomez also stated there is no one-to-one correlation between the degree of cortical involvement and the degree of retardation. Gomez Tr. at 62. Dr. Gomez testified that he did do an incomplete, unpublished study indicating a demonstrable correlation between the presence of many low attenuated lesions in infants less than one year old and the frequency and severity of seizures and mental retardation. Gomez Tr. at 101. He believes that if you do a brain scan of a child early in life, the more lesions that a child has, the more likely that the child is going to have seizures. The more cortical lesions the child has, the more likely that child is going to have severe neurologic dysfunction. Gomez Tr. at 102. If he took a subset of TS people with many multiple

brain lesions, the percentage of mental retardation would be much higher than 33 percent. Gomez Tr. at 104.

Dr. Gomez stated that DPT vaccine does not aggravate TS, but may aggravate the symptoms or bring them on. DPT impairs the vaccinee's normal development, including intelligence and the ability to acquire knowledge. Gomez Tr. at 88-89. TS can be very benign, so benign that a person does not know he or she has it. Gomez Tr. at 89. Dr. Gomez stated that pertussis immunization and infantile spasms have been linked for years. However, the proof has never been presented; they are linked by chronology. Gomez Tr. at 141.

Infantile Spasms

Respondent's defense is that TS, not DPT, is responsible for any seizures in a TS child if the child has eight or more tubers. In addition, respondent's defense is that DPT does not cause infantile spasms or any afebrile seizures. Congress did not differentiate among seizure types when it included RSD as a Table injury following DPT vaccination.[5]

Significant Aggravation

Congress defined "significant aggravation" as "any change for the worse in a preexisting condition which results in **markedly greater disability, pain, or illness accompanied by substantial deterioration of health** [emphasis added]." 42 U.S.C. §300aa-33(4). In order for this court to hold that DPT vaccine significantly aggravated a child's pre-existing TS, it must find that the child experienced greater disability, pain, or illness accompanied by a substantial deterioration of health whose onset was within Table time of the vaccination.

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[5]In a change of the Vaccine Table, effective March 10,1995, the U.S. Department of Health and Human Services ("HHS") removed RSD as a Table injury following DPT vaccination. 42 C.F.R. 100.1-100.3. In its discussion of infantile spasms and afebrile seizures, HHS reiterated its position: "The IOM concluded infantile spasms are not causally related to DTP vaccination. Therefore, there is no basis for a legal presumption of causation for this condition when it follows DTP vaccination.... The IOM concluded that afebrile seizures are not causally related to DTP vaccine." 60 Fed. Reg. 7678, 7690 (1995).

Legislative history provides insight into Congress' interpretation of "significant aggravation":

> The committee has included significant aggravation in the Table in order not to exclude serious cases of illness because of possible minor events in the person's past medical history. This provision does not include compensation for conditions which might legitimately be described as pre-existing (e.g., a child with monthly seizures who, after vaccination, has seizures every three and a half weeks), but is meant to encompass serious deterioration (e.g., a child with monthly seizures who, after vaccination, has seizures on a daily basis).

H.R. Rep. 98, 99th Cong., 2d Sess. 15-16, reprinted in U.S.C.C.A.N. 6344, 63 *56-57.* Apparently, Congress did not intend compensation for a slight increase in seizure frequency (from once monthly to once every three and a half weeks), but intended compensation for a serious deterioration, i.e., a marked increase in seizure frequency (from once a month to once a day).

Although Congress spoke in the above history of compensating significant aggravation of a minor illness, this court and others have held that petitioners may prevail even if their pre-existing illness was major, not minor, as long as the vaccination significantly aggravated it. Costa v. Secretary, HHS, No. 90-1476V, 1992 WL 47334 (Cl. Ct. Spec. Mstr. Feb. 26, 1992), vacated and remanded, 26 Cl. Ct. 866 (1992), on remand, 1992 WL 365421 (Fed. Cl. Spec. Mstr. Nov. 5, 1992); Suel v. Secretary. HHS, No. 90-955V, 1993 WL 241430, *7 (Fed. Cl. Spec. Mstr. June 18, 1993), rev'd and remanded on other grounds, 31 Fed. Cl. 1(1993); Green v. Secretary. HHS, No. 90-2847V, 1993 WL 141105, *9 (Fed. Cl. Spec. Mstr. April 19, 1993).

The language of the statute indicates that onset of an on-Table significant aggravation must occur within three days of a DPT vaccination. "Time period for first symptoms or

manifestation of onset or of significant aggravation after vaccine administration: ..3 days..." (emphasis added.) 42 U.S.C. §300aa-14(a).

Testimony at Omnibus Hearing

As part of its hearing on the common issues of TS, the court also heard in particular the cases of Michael Hanlon and Rachel Plavin so as to have specific details to which to apply the general defenses of respondent.

Michael Hanlon's onset of seizures (which the court previously held occurred within Table time of his DPT) occurred at the age of two months. His seizures were not infantile spasms. They were, however, afebrile. Michael has at least ten cortical lesions. Hanlon v. Secretary, HHS, No. 90-1013V, unpub. slip op. (Fed. Cl. Spec. Mstr. May 31, 1994).

Rachel Plavin (whose onset the court also found occurred within Table time) has forty abnormal cortical areas.[6] Her seizures were also not infantile spasms. They were, however, afebrile. Plavin v. Secretary, HHS, No. 91-1555 V, unpub. slip op. (Fed. Cl. Spec. Mstr. Dec. 29, 1994).

Dr. Steven H. Lamm, a pediatrician and epidemiologist, testified first for respondent during the October 8-11, 1996 Omnibus Hearing. Tr. at 55. He is board-certified in pediatrics, preventive medicine, and occupational medicine. Tr. at 57. He is a charter fellow of the American College of Epidemiology. Tr. at 58. He has done meta-analysis for ten years. Tr. at 62. His primary clients are industries, the government, and lawyers. Tr. at 66. He has done prior studies in lead and infant formula, leukemia in children, cholera in the Philippines, and birth defects (including Bendectin: he submitted an affidavit in the Daubert case). Tr. at 70-75, 88-89.

Dr. Lamm stated that to have evidence of causation between exposure to something and outcome, one must seek to

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[6] At the October 1996 hearing, Dr. Fitz testified that Rachel Plavin has at least 43 tubers.

explain the outcome by other factors and also show the outcome is significant. Tr. at 76. Epidemiologists look for data consistent with a causal hypothesis, unlike physicians, who, with a totality of information, reach a causal judgment. Tr. at 77. Epidemiologists look for 95% certainty. Tr. at 8 1-82.

As a medical epidemiologist, Dr. Lamm deals with the hypothesis that exposure leads to a disease. Tr. at 92. He organizes literature and data in the literature to see if there is a consistent pattern. Tr. at 92-93.

There are two types of epidemiologic studies: (1) case control studies, and (2) cohort studies. Tr. at 94. Case control studies are retrospective. Tr. at 95. They compare those with a disease to those without a disease and ask who was exposed to the material in question. Id. They calculate what are the odds of the case having or not having exposure. Id. Then they ask what are the odds of the control having or not having exposure. Id. A formula with the numerator consisting of the exposure odds of the cases over the denominator consisting of the exposure odds of the controls equals the odds ratio ("OR"):

$$\frac{\text{exposure odds of cases (people with the disease)}}{\text{exposure odds of controls (people without the disease)}} = \text{OR}$$

(Tr. at 99-100).

Cohort studies compare a group with exposure to a group without exposure and follow the subjects forward in time to see the ultimate outcome. Tr. at 94. They report the relationship between the two groups as relative risk ("RR"). Id.

The TS Omnibus Proceedings involve a case control study (being retrospective). Tr. at 104. Normally, in an odds ratio (OR), if exposure is the same in the case as in the control, the OR =1. Tr. at 97. If the OR is statistically significantly greater than 1, there is more likely an increased association between exposure and outcome. Id. If the OR is less than one, the people with the disease are less likely to have been exposed than the people without the disease. Tr. at 101.

The P value also expresses certainty by measuring the

probability that the results could have happened by chance alone. Tr. at 103. If the P value is less than 05, the confidence level is more than 95%. Tr. at 102.

"Statistical significance" is the standard terminology for epidemiologic analysis. Tr. at 101. A P value of less than .05 is statistically significant. Tr. at 102. Confidence limits are the same as the confidence interval (CI). Tr. at 107-08.

Epidemiology permits comparison of ratios, for example, comparing exposure odds of cases to exposure odds of controls. Tr. at 112. This entails use of a "two-by-two" table wherein the epidemiologist assigns someone to one of four cells in order to develop comparison rates. Tr. at 113-14.

Two-By-Two Table

R. Trial Ex. B. depicts the cells as with the disease and exposure on the top left, without the disease and with exposure on the top tight, with the disease and without exposure on the bottom left, and without the disease and without exposure on the bottom right:

with disease; with exposure	without disease; with exposure
with disease; without exposure	without disease; without exposure

If cases are more likely to be exposed than non-cases, Dr. Lamm then asks if the OR is statistically significant. Tr. at 116.

Dr. Lamm wrote two papers as a result of his work as an expert in this case. The first is entitled "Cortical Tuber Count: a Biomarker indicating Cerebral Severity of Tuberous Sclerosis Complex," by M. Goodman, S.H. Lamm, A. Engel, C.W. Shepherd, C.W. Houser, and M.R. Gomez[7] ("Tuber Count article".) R. Ex. LL.

The second article is a draft dated September 19, 1996, entitled "Temporal Relationship Between Date of Onset of

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[7]This was subsequently published as Goodman, M. et al. "Cortical Tuber Count: A Biomarker Indicating Neurological Severity of Tuberous Sclerosis Complex," 12 J Child Neur 85 (1997). R. Ex. DDD. This was followed by an editorial entitled, "Tuberous Sclerosis: Function Follows Form," by E.S. Roach, 12 J Child Neur 75 (1997). R. Ex. DDD.

Infantile Spasms and Prior Immunization with DPT and/or DT: An Analysis Based on the Data from the National Childhood Encephalopathy Study," by M. Goodman, S.H. Lamm, and M.H. Bellman. R. Ex. MM. ("Reevaluation of Bellman" article.) Respondent has informed the court that this second article has been accepted for publication by the journal Vaccine.[8]

To begin his analysis, Dr. Lamm and his staff performed a TS literature review and eventually identified the best of the population studies and of the clinical studies. Tr. at 132-33. He found Dr. Osborne's study to be the best population study.[9] The best clinic-based study is Dr. Gomez's study at the Mayo Clinic.[10] Dr. Lamm found that the two studies' findings were analogous. Tr. at 139. Of the 131 TS cases in Webb '96, 70 had a learning disorder which equals 53.4%. Tr. at 137. Ninety-nine of the cases had seizures, with 70 of the patients with a known age of seizure onset having the onset within the first year of life (71%). Id. The Mayo Clinic study included 75 TS patients and the findings were that 41 of the 75 (55%) had mental impairment and 66% of those whose age at onset of seizures was known had onset of their seizures within the first year of life. Tr. at 139. The Mayo Clinic study also includes an additional analysis—the relationship between tuber count and mental disability, and tuber count and seizure onset before age one. Id.

Dr. Lamm cut the Mayo Clinic data at the median number of tubers for the TS cases, which was ten tubers. Tr. at 157. Of the 75 cases, 39 had ten or more tubers and 36 had less than 10 tubers. Id. Based on his analysis, Dr. Lamm testified that

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[8]Respondent file an earlier draft of the same Bellman reevaluation, dated November 28, 1995. R. Ex. W.

[9]Webb et al., "Morbidity Associated with Tuberous Sclerosis: A Population Study," 38 Develop Med and Child Neur, 146-5 1 (1996) ("Webb '96"). P. Ex. 59.

[10]Shepherd et al., "MR Findings in Tuberous Sclerosis Complex and Correlation with Seizure Development and Mental Impairment," 16 AJNR 149-55 (Jan. 1995) ("Mayo Clinic"). R Ex. 0.

someone with bad TS, i.e., mental retardation, is four and one-half times more likely to have a high tuber count (ten or more tubers). Tr. at 158. The confidence interval is from 1.5 to 13.4; thus, 1.0 is not in the confidence range and the results are statistically significant. Tr. at 158-59. The risk may be as low as 1.5% or as high as 13.4% but the best estimate is 4.5%. Tr. at 159. The P value is less than 5% which means that there is a less than one in twenty chance that the numbers could have occurred at random. Tr. at160. The P value here is .004 which says that there is a 1 in 250 chance that the association is random. Id.

Dr. Lamm also performed an OR for seizure status (defined as onset prior to one year). Tr. at 162. For cases with ten or more tubers, the OR was 9.7 with a lower confidence limit of 2.9 and an upper confidence limit of 35.1. Id. The narrower the range of the confidence interval, the less uncertainty. Tr. at 163.

Dr. Lamm then cut the Mayo Clinic data at those having eight or more tubers, and those having 0-7 tubers. Tr. at 165-66, 169. He and his colleagues concluded that seven tubers or less meant there was no statistically significant correlation between tuber count and ultimate outcome (seizures and mental retardation). Tr. at 169-70. Those with eight or more tubers had a three times greater chance of mental retardation than those with 0-7 tubers, with an OR of 3.2 and a low range in the confidence interval of 1.1 which is still statistically significant. Id., R Trial Ex. C at 16.

The OR for people with eight or more tubers and seizure status was 9.1 so that the TS cases at the Mayo Clinic with seizures were more than nine times likely to have eight or more tubers than the people without seizures. Tr. at 170, R. Trial Ex. C at 16.

Dr. Lamm concluded that cortical tuber count is a strong factor relating to mental retardation and seizure status. Tr. at 171. His conclusion is based on the OR and its confidence levels and the P values; the sequential analysis at different cuts; and his finding that his conclusion was characteristic of the data, and not

characteristic of his analysis. Tr. at 179.

Dr. Lamm then went on to perform a meta-analysis to determine if his finding was representative of the whole body of information that exists. Tr. at 180. He teaches meta-analysis on the graduate level. Tr. at 180. The title of his course is "Where the Whole is Greater than the Sum of the Parts". Tr. at 180. He stated that the medical community accepts meta-analysis basically, although it is criticized within the profession. Tr. at 182. Meta-analysis is very common in medicine. Tr. at 184. Dr. Lamm started with the hypothesis that bad outcome of TS is associated with a high tuber count. Tr. at 186. He then proceeded to find studies which identified TS individuals with cortical tuber counts by MRI, who were classified by mental impairment and seizure status. Tr. at 186. Three cardinal words are inclusion, exclusion, and independent as criteria for meta-analysis. Tr. at 188.

Inclusion means one starts out broadly with every study with relevant data. Tr. at 188. He developed criteria for his categories and separated out the studies that do not fit the criteria to engage in exclusion. Tr. at 189. If two studies included the same population he would not use both of them, thus maintaining the independence of the cases. Id.

In discussing Dr. Lamm's cortical tuber paper, the court will refer to R. Ex. DDD (the published version in a peer-reviewed journal) rather than R. Ex. LL (the draft from which Dr. Lamm testified in October 1996). The authors found five studies that met the criteria for examining the association between the number of cortical tubers on MRI and severity of cerebral dysfunction. Tr. at 191. Lamm et al. conclude that the MRI-detected cortical tuber count TS is six times more likely to be above the median count (which is different in each study) for TS patients with severe cerebral dysfunction than TS patients with more mild affects. Tr. at 195. When they cut the data in all five studies at eight or more tubers, they found that moderately to severely affected TS patients were 5.3 times more likely to have eight or more tubers than those with mild TS and those with

seizures were 16 times more likely to have eight or more tubers than those without seizures. Tr. at 196. The associations were statistically significant. Id. The authors thus concluded that cortical tuber count was a biomarker to predict the severity of functioning and the presence of seizures in a TS patient. Tr. at 223.

The five studies that were part of the meta-analysis were: Roach et al.,[11] Inoue et al.,[12] Jambaque et al.,[13] Menor et al.,[14] and Shepherd et al.[15]

In Roach's 1987 paper, nine TS patients who had ten or more cortical lesions had both severe developmental delay and poorly controlled seizures. R. Ex. M, p. 303.

In Inoue's 1988 paper, the severely mentally retarded among ten TS patients tended to have more subcortical lesions. R. Ex. AA, p. 379.

In Jambaqué's 1991 paper, among 23 TS children, seven were normal, ten were mentally retarded, and six were mentally retarded with autism. R. Ex. L, pp. 699-700. The number of tubers on MRI ranged from one to eight. Id. at 700. Eleven children had more than eight tubers. Id. Among sixteen children

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[11]Roach, E.S., Williams, D.P., Laster, D.W., "Magnetic resonance imaging in tuberous sclerosis," 44 Arch Neur 301-03 (1987). R. Ex. M.

[12]Inoue, Y., Nakajima, S., Fukuda, T., et al., "Magnetic resonance images of tuberous sclerosis. Further observations and clinical correlations," 30 Neuroradiology 379-84 (1988). R. Ex. AA.

[13]Jambaque, I., Cusmal, K., Curatolo, P., et at., "7NeuropsychologiCal aspects of tuberous sclerosis in relation to epilepsy and MBJ findings," 33 Dev Med and Child Neur 698-705 (1991). R Ex. L.

[14]Menor, F., Marti, B.L., Mulas, F., et a.,"Neuroimaging in tuberous sclerosis: A clinicoradiological evaluation in pediatric patients," 22 Ped Radiol 485-89 (1992). R. Ex. BB.

[15]Shepherd, C.W., Houser, 0.W., Gomez, M.R., "MR findings in tuberous sclerosis complex and correlation with seizure development and mental impairment," 16 AJNR 149-5 5 (Jan. 1995). R. Ex. 0.

with IQs of less than 65, one had one lesion and two had two lesions, but most had multiple bilateral cortical tubers. Id. at 701. All in this group had had partial seizures or persistent infantile spasms and later developed severe or intermediate multifocal epilepsy. Id.

Among those TS patients with four or more tubers was one person who had an IQ of 85-110, six people who had an IQ of 40-65, and seven people who had an IQ of less than 40. Id. at 702. Among those who had from zero to two tubers was one TS patient with an IQ of less than 40, two with an IQ of 40-65, and six with an IQ of 85-110. Id. The only TS patients with autism were six who had four or more tubers. Id. Among those with four or more tubers were six with severe epilepsy and seven with intermediate epilepsy. Id. However, one TS patient with severe epilepsy had from zero to two tubers. Id.

Jambaqué and his co-authors state that mental retardation occurs in 47 to 56 percent of TS patients. Id. All reported TS patients with severe mental retardation had early-onset epilepsy, mainly West syndrome (which includes infantile spasms). Id. Several attempts have been made to identify specific topographical lesions with brain deficits such as autism. Id. at 703. The authors surmise that "[b]oth the number and the topography of tubers seem to play an important role in mental outcome. This supports the idea that both epilepsy and mental retardation reflect the cerebral dysfunction caused by cortical tubers." Id.

In Menor's 1992 paper, the authors concluded after analyzing twenty-seven TS patients that there was no clear relationship between radiological features and the patients' neurological evolution. R. Ex. BB, p. 485. Among these patients, 59 percent were retarded in mental development, 26 percent were borderline, and 15 percent were normal. Id. at 486. Half the six patients with more than five cortical tubers and half the twelve patients with more than ten cortical tubers showed a good neurological evolution. Id. at 487. One patient without

cortical tubers and one with fewer than five cortical tubers had poor control. Id.

Menor and his co-authors state that central nervous system manifestations often occur before one year of age. Id at 488. Ninety-six percent of the patients had seizures as the earliest and most common neurological manifestation of TS. Id. at 489. Mental retardation, although variable, was usually in fifty percent of the patients. Id. The authors conclude, "In patients with TS, it is not possible to predict their clinical prognosis by neuroimaging:" Id.

In Shepherd's 1995 paper, the authors (including Dr. Manuel Gomez) conclude that the number and anatomic location of cortical tubers may play an important role in the mental development and thus the intelligence of TS patients. R. Ex. 0, p. 149. An additional correlate to mental disability is the age of seizure onset. Id. at 149-50. Cortical tubers may be asymptomatic, but often are associated with severe intractable seizures and mental disability. Id. at 149.

Significantly more tubers were found in patients whose seizures began before one year of age and who were mentally disabled. Id. Patients who had infantile spasms had a greater number of tubers as well. Id. They studied seventy-five patients. Id. at 150. The number of tubers ranged from one to forty-six. Id. at 152. The likelihood of a first seizure being an infantile spasm increased with the total number of tubers. Id.

Twenty-seven of the twenty-nine patients with infantile spasms had a median number of 4.4 tubers. Id. Twenty-five of these twenty-seven patients were impaired. Id. Twelve of the twenty-six patients with generalized seizures had a median number of 3.3 tubers. Id. Thirteen of these twenty-six were impaired. Id. Eight of the fifteen patients with partial seizures had a median number of 1.3 tubers. Id. Six of these fifteen were impaired. Id. Four of five patients with no seizures had a median number of 1.8 tubers. Id. None of these five was impaired. Id.

Fourteen patients had seizure onset before the age of three

months. Id. These fourteen had an average number of 19.2 cortical tubers. Id. Twenty-one patients had seizure onset between the ages of three to six months. Id. These twenty-one had an average number of 19.8 cortical tubers. Id. Eleven patients had seizure onset from six to twelve months. Id. These eleven had an average number of 15.7 tubers. Id. Sixteen patients had seizure onset from twelve to sixty months. Id. These sixteen had an average number of 16 tubers. Id. Eight patients had seizure onset at over five years of age (over sixty months). Id. These eight had an average number of seven tubers. Id.

The authors conclude from this data that patients with seizure onset before six months of age had three times as many tubers as patients whose seizures began after one year of age.[16] Id.

Forty-one patients were mentally disabled; they had an average number of 18.2 tubers each. Thirty-four patients did not have disability; they had an average of 9.9 tubers each. Id. at 152-53. The authors state, "The possibility of a patient being mentally disabled was directly related to the total number of tubers." Id. at 153.

The MRI underestimated the number of cortical tubers. Id. In the seven children younger than two years of age, the number of tubers was lower than the actual number because the brain

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[16]The data may prove too much, however, since respondent's position is that having eight or more tubers leads to a bad outcome, yet testimony and the medical articles state that if a child reaches one year of age without onset of seizures, he is much better off clinically. In fact, according to the Shepherd data, eight children with an average of seven tubers had seizure onset after the age of five years. R. Ex. 0 at 52. A doctor would not expect a bad outcome in a brain that had developed normally for five years. For example, petitioners' expert, Dr. John Osborne, in one of his articles, states, "It is our experience that individuals who reach 5 years of age with normal development do not develop mental handicap from tuberous sclerosis...." Webb, D.W., Thomson, J.L.G., Osborne, J.P., "Cranial magnetic resonance imaging in patients with tuberous sclerosis and normal intellect," 66 Arch Dis Childhood 1375-77, 1376 (1991). P.'s Ex. 65. The Shepherd cut-off for clinical abnormality is substantially higher in tuber count (18.2 on average) than the respondent's number of eight or more. R. Ex. 0 at 152-53.

needs greater myelination for MRIs to detect tubers and this requires maturation beyond two years. Id. The authors found that tubers cause epilepsy because there was clear topographic correlation between EEG spike foci and areas of abnormal MRI signals. Id.

The number of tubers found in the patients with TS were largely different. Id. The frontal and parietal lobes were most commonly involved. Id. The authors found more tubers in the frontal, medial, parietal, and temporal lobes of TS patients who had infantile spasms than in those TS patients with other types of generalized seizures or partial seizures. Id. Statistically, occurrence of infantile spasms and not another type of seizure was related to the total number of tubers, not to geographic location. Id. Eighty-six percent of the patients (twenty-five out of twenty-nine) with infantile spasms were disabled. Id. The authors conclude that the greater number of cortical tubers in TS patients with infantile spasms "causes more cerebral disruption and deficit." Id.

Patients with other types of generalized seizures had fewer tubers than those with infantile spasms but more than those with partial seizures. Id. Sixty percent of the patients (nine out of fifteen) with-partial seizures were mentally disabled. Id. They had fewer tubers in the frontal lobes than those with infantile spasms. Id. at 153-54. There was a direct relationship between number of tubers and possibility of mental disability. Id. at 154.

The authors also state that all TS patients with mental disability had or have some type of seizure, usually generalized and very often infantile spasms. Id. None of the five patients who had never seized was mentally disabled. Id. Yet, they had a median number of cortical tubers that was higher than that for the patients with partial seizures. Id In addition, the average number of frontal lobe tubers in the seizure-free group of five patients was higher than for those with partial or generalized seizures, excluding those with infantile spasms. Id. From these data, the authors conclude that if a TS patient has mental disability,

seizures are always associated with it, "suggesting that the seizures themselves play a role in the pathogenesis of the mental impairment."

Referring to Roach et al., the authors state that Roach was unable to link directly intelligence and the number of tubers. Id. The authors surmise part of the difficulty may lie in Roach's use of less sensitive equipment. Id. In criticism of Jambaqué, the authors write that Jambaque' did not state the total number of tubers accurately in relating number of tubers to mental development, especially in cases of infantile spasms. Id. Jambaqué's study had three patients with unfavorable outcome who had fewer than two tubers. Id. Moreover, Jambaqué's study did not give a complete picture because it did not describe anyone with generalized seizure other than infantile spasms. Id.

Because MRIs were not done at the same time as seizure onset, Shepherd and his coauthors could not assess how MRIs could be used to predict future disability. Id.

In Dr. Lamm's published paper based on these five papers, he and his co-authors (including the three authors of the Shepherd paper) state that severe mental retardation is seldom seen in TS patients whose seizure disorder presents after infancy and is not seen in those who do not seize. R. Ex. DDD at 85. "The relationship between cortical tubers, seizures, and mental retardation is not well defined." Id. at 86. The hypothesis Dr. Lamm presented was whether the tuber count in the above five studies of TS patients was predictive of the patients' neurodevelopmental status (normal or abnormal) or seizure status (normal or abnormal). Id. The studies demonstrate increased severity of both developmental status and seizure status with increased number of cortical tubers. Id. at 87.

Lamm and his co-authors conclude that TS patients with more cortical tubers were about six times as likely to have intermediate or severe developmental delay and about eighteen times as likely to have poor seizure control than those with fewer cortical tubers. Id. at 87-88. TS patients with eight or more tubers

were about five times as likely to have intermediate or severe developmental delay and about sixteen times as likely to have poor seizure control than those with fewer cortical tubers Id at 88.

One of the articles in the area which Dr. Lamm and his co-authors did not use because the subjects of the study with tuber counts were of normal intelligence was "Cranial magnetic resonance imaging in patients with tuberous sclerosis and normal intellect," by David W. Webb, J.L.G. Thomson, and J.P. Osborne (the last being petitioners' witness) in 66 Arch Dis Childhood 1375-77 (1991). P. Ex. 65. Tr. at 234. In that study, Dr. Osborne and his co-authors conclude that MRI count of tubers is "unlikely to be a reliable predictor of clinical outcome." P. Ex. 65 at 1376. A better predictor may be distribution and size of lesions. Id. None of their eleven patients under MRI analysis had more than ten cortical tubers. Id. One of their patients, who was a bright student, had nine cerebral tubers. Id. Others have been reported with considerably fewer lesions but with severe mental handicaps. Id.

In conclusion, Dr. Osborne and his co-authors state, "[o]ur findings suggest that the wrong conclusions may be drawn if the number of lesions alone on cranial MRI is used to predict neurological outcome in tuberous sclerosis." Id. at 1377. They suggest that future studies include number, size, and distribution of lesions. Id.

Dr. Lamm's study includes only cortical tuber count, not size or distribution. R. Ex. DDD. The same criticism that Dr. Osborne and his co-authors raised in their paper (P. Ex. 65) is expressed in an editorial following Dr. Lamm's paper on cortical tuber count as a biomarker for neurological severity: "Tuberous Sclerosis: Function Follows Form," by E.S. Roach, 12 J Child Neur 75-76 (1997). R. Ex. DDD (following the Lamm paper). Dr. Roach states:

> Given the variability of both the neurologic impairment and the brain pathology caused by tuberous sclerosis, it seems reasonable that

> children with more brain lesions should have more severe neurologic impairment.... Despite a trend toward greater severity with increasing numbers of cerebral lesions..., individual patients may not fit this pattern. Many of us have encountered a well-functioning patient whose scan is quite abnormal or a child whose scan is only mildly abnormal despite very impaired function.
>
> [E]xtensive brain disruption by tuberous sclerosis may predetermine which patients develop intractable epilepsy and through this or other mechanisms contribute to poor intellectual development.

Id., at 75-76.

Continuing in his criticism, Roach states that although Lamm's analysis is convincing. "a correlation of this sort leaves many unanswered questions. There is enough individual variation of both the clinical outcome and the radiographic appearance that the magnetic resonance scan alone generally cannot be used to establish the prognosis for an individual patient." Id. at 76. In addition, seizure control may not be the only influence on a child's developmental outcome because distribution of brain lesions in specific regions may affect behavioral or cognitive patterns. Id. To determine this "will require careful comparison of the number, size, and location of the cerebral lesions" of TS together with detailed neuropsychological testing. Id.

The undersigned has or has had before me thirty TS cases. I have a tuber count for 19 of those cases. The least number of

tubers is four[17] the greatest number of tubers is forty-three.[18] But there is no clear-cut correlation between number of tubers and developmental delay. For instance, Miller[19] has ten tubers and has serious developmental problems and substantial deficits. But Destry Decker[20] has seventeen tubers, yet his IQ is in the low normal range and he planned to graduate high school and attend college. His brother, Damien Decker,[21] however, has twenty-three tubers and has elective mutism and mild retardation with emotional problems. In comparison, Turner[22] has thirteen tubers, ten less than Damien, but he cannot talk or feed himself and has a stomach tube. In 1989 when he was 11 years old, he had a mental scale of six months and a motor scale of fifteen months. Drs. Osborne's and Roach's separate criticisms of reliance solely upon cortical tuber count in predicting neurological outcome, without evaluating tuber location and size, seems appropriate. This emphasis on size and location is in the Shepherd et al. paper as well. R. Ex. 0.

The second major part of Dr. Lamm's testimony dealt with the question of whether DPT is a significant risk factor for bad TSC. Tr. at 291.

In Dr. Lamm's testimony, he referred to the Melchior

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[17] Henkel, No. 90-33 14V. The child had infantile spasms, but is functioning well albeit some significant delay in a couple of areas.

[18] Plavin, No. 91-1555V. She is functioning at a low to moderately low level and the latest development record shows her about two years behind in gross and fine motor skills.

[19] No. 90-2764 V.

[20] No. 90-1115V.

[21] No. 90-1116V.

[22] No. 90-3409 V.

study in 1977[23] as proof that DPT does not cause infantile spasms. Tr. at 296. When Denmark changed the immunization schedule from the fifth month to the second month, the onset of infantile spasms remained the same. Id.

Before April 1, 1970, DPT was administered in Denmark at five months, six months, and fifteen months of age. R. Ex. H at 134. After April 1, 1970, pertussis vaccine was administered at five weeks, nine weeks, and ten months of age. Id. Melchior compared the onset of 86 cases of infantile spasms from 1957 to 1967 with the onset of 113 cases of infantile spasms from April 1, 1970 to March 31, 1975, and found "no significant difference" in the age of onset. Id. at 134-35. He stated, however, there might be a few cases of causal connection from the vaccine. But, he thought "time-coincidence the most likely factor." Id. at 136.

Dr. Lamm's second article concerned a re-evaluation of the Bellman 1983 paper.[24] Bellman and his co-authors took the 269 infantile spasms cases reported in the National Childhood Encephalopathy Study (NCES)[25] and conducted a case control

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[23]Melchior, J.C., "Infantile spasms and early immunization against whooping cough. Danish survey from 1970 to 1975," 52 Arch Dis Childhood 134-37(1977). R. Ex. H.

[24]Bellman, M.H., Ross, E.M., and Miller, D.L., "Infantile Spasms and Pertussis Immunization," The Lancet 1031-34 (May 1983). P. Ex. 53.

[25]Alderslade, K., Bellman, M.H., Rawson, N.S.B., Ross, E.M., and Miller, D.L., "The National Childhood Encephalopathy Study: A report on 1000 cases of serious neurological disorders in infants and young children from the NCES research team," Department of Health and Social Security, Whooping Cough: Reports from the Committee on the Safety of Medicines and the Joint Committee on Vaccination and Immunisation (London Her Majesty's Stationery Office, 1981). P. Exs. 80 and 80A. According to the Institute of Medicine (IOM), the NCES did not include infantile spasms in its study of DPT because "post-hoc analyses show[ed] no association between infantile spasms and earlier DPT immunizations." DPT Vaccine and Chronic Nervous System Dysfunction. A New Analysis, IOM (Washington, DC: National Academy Press, 1994) at 8. P. Ex. 82A. Actually, this is an oversimplification. The NCES did include infantile spasms, but found that the same incidence of onset occurred after DPT as after DT and, since the overall number of onsets of neurological illness after DT was not statistically significant, it could similarly not find the incidence of

analysis. P. Ex. 53 at 1031. They found an antecedent factor that may have caused infantile spasms in 34 percent of the cases. Id. The two most common causes were perinatal hypoxia (38 cases) and TS (16 cases). Id. The authors conclude that DPT does not directly cause infantile spasms, but may precipitate their onset "in those children in whom the disorder is already destined to develop." Id. at 1033.

Bellman and his co-authors classified the children into one of three categories: symptomatic (92 children) for those with an antecedent disorder that could cause the spasms; cryptogenic (163 children) for those with no apparent cause; and doubtful (14 children) for those whose prior development was not normal but who had no definite antecedent factor. Id. at 1031. The symptomatic group was subdivided into perinatal and postnatal groups and a group with congenital or genetic conditions. Id. TS was included in the congenital/genetic subgroup of which it was the most common in that subgroup (16 out of 35 cases). Id.

The authors state that since the onset of infantile spasms occurs when most infants are receiving immunizations, "a temporal coincidence would be expected in a certain number of cases." Id. at 1033. In Denmark and Japan, when the age of vaccination was reduced, the incidence of infantile spasms onset did not change, suggesting that causal association was unlikely. Id. The NCES did not show any significant association between infantile spasms and DPT administered in the prior seven days. Id.

However, there was a small excess (less than 10 percent) in the number of cases over those in the control group in seven days after vaccination, with a corresponding deficit in the next three weeks, suggesting that both DPT and DT may trigger the onset of spasms. Id. Most of the DPT-associated cases were cryptogenic whereas most of the DT-associated cases were

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infantile spasms by itself after DPT statistically significant. P. Ex. 80A. Bellman's 1983 paper based on the NCES data shows the same result of equal incidence of infantile spasms after DPT and DT. P. Ex. 53.

symptomatic. Id. A high proportion of the TS (symptomatic) cases were vaccine-associated. Id. This suggests TS cases were associated with DT, rather than DPT, vaccine.

In Dr. Lamm's re-evaluation of the Bellman paper, he included Dr. Bellman as a coauthor. R. Ex. MM. The data were the same underlying the 1983 Bellman paper. The authors of the 1996 re-evaluation propose three models: triggering of a hypothetical relationship between DPT or DT and the onset of infantile spasms: (indistinguishable from causality); recruitment (onset would have occurred anyway, but occurs sooner); and no-effect. Id. at 8.

They found no association between DPT or DT exposure in the prior month and the onset of infantile spasms. Id. at 9. However, among this group with DPT or DT exposure in the previous month, cases were most likely to be reported within one week of exposure than within the other three weeks of the preceding month. This observation fits within the recruitment effect model. Id.

The authors included TS patients in the category of previously abnormal. Id. at 10. The data for the previously abnormal infantile spasm cases with DPT or DT exposure fall into the noeffect model. Id. None of the data fit the triggering model. Id.

Dr. Lamm referred in his testimony to an abstract of data that Dr. Sergiusz Jozwiak submitted. Tr. at 353, R. Ex. FF.[26] In the October 1996 portion of the Omnibus hearing, this was all the information that respondent provided the court. Consequently, the court asked that respondent file the full paper when available. As a result of the filing of this paper (with Drs. Lamm and Goodman as co-authors), the court continued testimony on the Omnibus

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[26]Jozwiak, S., Chmielik, J., and Michatowicz, K., "Seizures and Intellectual Disability in Children with Tuberous Sclerosis," 37 Supp. 4 Epilepsia 126 (1996).

issues in June 1997.[27]

In the abstract, Dr. Jozwiak states that 85-90 percent of TS patients have epileptic seizures, and frequently mental retardation. R. Ex. FF at 126. From 1984-95, he and his coauthors examined 106 Polish children with TS, 102 of whom had epilepsy. Id. In almost 60 percent of the patients, onset of seizures occurred in the first six months of life; in 75 percent of the children, onset occurred within the first year. Id. Most frequently, onset of seizures occurred between the ages of 2 and 6 months, usually as infantile spasms. Id. Those children who seized early more often had severe mental retardation. Id. To test whether or not DPT affected onset of seizures, the authors separated out twenty children who had not been vaccinated. Id. All of them developed seizures, 16 of them between the ages of 3 and 5 months. Id. Of 86 TS children vaccinated with DPT, 82 of them developed seizures at the same age as the unvaccinated TS children. Id.

Although the Jozwiak data rely on a small number of children and, thus, the data are not statistically significant, it is the only medical study that deals specifically with TS children and DPT vaccine. Tr. at 354-55, 361-62. It does not deal with tuber counts or types of seizure. Tr. at 355, 357.

There is another study by a psychologist, Ann Hunt, in 1983 in England.[28] She sent out 150 questionnaires to TS families and received 97 replies. R. Ex. K at 346. The TS individuals ranged in age from one year to age 51. Id. Fifteen had never seized. Id.

Infantile spasms were the first symptom in 66 of the 82 cases. Id. at 347. Ms Hunt divided the cases into four groups according to their immunization status. Id. at 346. Group II

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[27]The paper was submitted on May 13, 1997 as R. Ex. EEE. Sergiusz Jozwiak, Michael Goodman, and Steven H. Lamm, "Poor Mental Development in TSC Patients: Clinical Risk Factors." It has been accepted for publication in Arch Neur

[28]Hunt, Ann, "Tuberous Sclerosis: A Survey of 97 Cases. I. Seizures, Pertussis Immunization and Handicap," 25 Developmental Medicine & Neurology 34649 (1983). R. Ex. K.

(children immunized after seizure onset) was further divided according to whether the vaccinee received DPT or DT. Id. at 348. She found that six of the 13 DT vaccinated children were profoundly handicapped compared with two of the 14 DPT vaccinated children. Id. She concluded that the severity of these children's condition had to be related to factors other than pertussis vaccine.[29] Id. Early onset of seizures was predictive of poor outcome. Id. at 349. She opines that DPT as well as other factors (teething, high temperature, polio vaccine, smallpox vaccine, etc.) may act as triggers to seizure onset. Id.

In describing R. Ex. EEE, the Jozwiak paper, Dr. Lamm testified on June 3, 1997 that Dr. Jozwiak sent him data which he analyzed. Tr. at 1563-64. Among four risk factors (age at seizure onset, gender, previous DPT immunization, and seizure type), Jozwiak, Goodman, and Lamm concluded that only seizure type had a statistically significant association with poor mental development. R. Ex. EEE at 2. The authors also found that age of seizure onset was significantly associated with poor mental development until they "adjusted for seizure type," i.e.,removed infantile spasms from their calculations.[30] Id. at 13-14. Neither gender nor prior DPT vaccination was a risk factor for poor mental development. Id. at 14.

Poland's DPT immunization policy is that the first DPT is administered at three months, the second six weeks later, and the third six weeks after that. Id. at 4. The fourth DPT is given between the ages of 1½ to 2 years. Id. The authors compared seizure onset during the first four months of life for those who had prior DPT vaccinations with those who did not (20 patients).

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[29]Group III contained those people vaccinated within one month prior to seizure onset. Of these 17 people, only two were profoundly retarded. R. Ex. K at 346, 348.

[30]The authors, viewing infantile spasms as age-specific since they occur only between three and eight months of age, removed them from their calculations, leaving seizure onset of the remaining seizure types, and found that these seizures (non-infantile spasms) were unrelated to poor outcome. Tr. at 1592-94.

Id. at 7-8. Eighteen of the twenty infants with seizure onset and no prior DPT had their seizure onset within their first four months, the same age as those infants with prior DPT immunization. Id. at 11. The authors conclude that DPT has no association to the onset of seizures in TS children. Id. at 13.

Eighty-five percent of patients who seized within the first six months of life had infantile spasms. Id. at 13. The authors conclude that the most important single clinical finding associated with poor mental development is infantile spasms. Id. They comment that the Webb et al. family-based study[31] reports a lower rate of mental abnormalities because the authors excluded from their study spontaneous mutations, which cause approximately 60 percent of all TS cases. Id. at 12.

In his testimony in October 1996, Dr. Lamm stated that 55 percent of TS patients at the Mayo Clinic who had MRIs had mental retardation, and 72 percent of those with ten or more tubers were mentally retarded. Tr. at 449. In his testimony in June 1997, Dr. Lamm said that there is a fourfold increased risk of moderate to severe mental retardation if a TS child has infantile spasms. Tr. at 1586-87.

Dr. John P. Osborne testified for petitioners in October 1996. Tr. at 460. He is a consultant pediatrician with a special interest in pediatric neurology and TS. Tr. at 461-62. He has done research in the morbidity of TS and is continuing to study TS patients. Tr. at 466-68. He is also a medical adviser to the TS Society of Great Britain. Tr. at 471-72.

Dr. Osborne testified that no one knows the causative mechanism of seizures in TS. Tr. at 475. A TS child will be neurologically handicapped only if he or she has seizures unless there is another cause. Id. As the tuber count increases, in general the risk of mental retardation increases. Tr. at 476-77. However, he is not convinced that tuber count has as close a relationship to bad outcome as Dr. Lamm testified. Id. Other

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[31] Webb, D.W., Fryer, A.E., and Osborne, J.P., "On the incidence of fits and mental retardation in tuberous sclerosis," 28 J Med Genet 395-97 (1991). P. Ex. 63

factors, such as gender, and size and location of the tubers, come into play. Id.

Dr. Bellman used data from the NCES[32] in his 1983 paper. Tr. at 486. The NCES was designed to examine the role of DPT in the outcome, but not to look at infantile spasms, just at encephalopathy. Id. In Dr. Osborne's view, there was a gross underestimate of the number of infantile spasms post-DPT because they were not reported. Id. The number of TS children in the study also grossly underestimated the number they should have found over the study's time period. Tr. at 487.

TS children have normal development before seizures. Id. There is a great debate over which category to put non-symptomatic TS children: normal or abnormal. Tr. at 487-88. Dr. Osborne would look at TS cases separately, but there was too small a group to have significant results from the NCES data. Tr. at 488. Dr. Bellman's 1983 paper was very good, but had its problems and limitations. Tr. at 489.

In Dr. Osborne's opinion, anything might recruit seizures. Tr. at 499. It is difficult for him to say, however, that DPT causes afebrile seizures in a TS child. Tr. at 500-01. It is possible that whatever triggers seizures can be a cause, such as swelling at the vaccine site. Tr. at 501-02. The general trend is that the more tubers, the more the risk of seizures and mental retardation. Tr. at 510.

As a rare occurrence, DPT can cause encephalopathy in normal children. Tr. at 512. DPT is a risk factor for TS children because one wants to avoid giving them a fever. Tr. at 516. The earlier their seizures, the more risk of retardation. Tr. at 519. The risk of a low IQ is higher with an earlier age of onset, i.e., within the first year. Tr. at 521. He has seen children who have TS and are on anticonvulsants contract a fever and not seize. Tr. at 535. He is uncertain if TS patients can withstand a fever without seizing prior to treatment with anticonvulsants. Tr. at 535-36. He

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[32] See supra, note 25.

thinks Dr. Lamm's cortical tuber paper is misleading because it omits confounding factors. Tr. at 536. It is difficult to answer in an individual child whether DPT caused his or her seizures. Tr. at 548. There is no way of knowing. Id. He could not rule out DPT as a cause, however. Tr. at 550. Half of TS children are likely to have mental retardation; three-quarters of them are likely to have seizures. Tr. at 555.

There are two gene sites (TSC 1 and TSC 2) for chromosomes linked to TS: chromosome 9 and chromosome 16.[33] Tr. at 565. Dr. Osborne stated that TS is not an idiopathic condition. Tr. at 567. He does not think he has seen a child with more than nine tubers who was normal. Tr. at 587.

Dr. Osborne testified that TS causes infantile spasms, which can have an acute onset. Tr. at 593-94. There is clearly an association with TS, but no one knows how TS causes infantile spasms. Tr. at 594. TS also causes mental retardation. Tr. at 596. In less than ten percent of the cases would he attribute the cause of seizures in a TS child to something other than TS. Tr. at 596-97. A febrile illness could cause seizures in a TS child, but it would not have sequelae. Tr. at 596.

Seizures cause the damage in the TS child. Tr. at 609-10. Three to six months is the most common age for TS children's onset of seizures. Tr. at 611. To have onset of seizures at nine months is better than at three months. Id. The number of tubers does not fully predict the outcome. Tr. at 628. Age and gender are risk factors for seizure onset. Tr. at 630. DPT is not the most important variable and is not frequently the cause of seizures in a TS child. Id. DPT has an influence in some children. Tr. at 631. But in an individual, one cannot tell if DPT caused the seizure. Id.

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[33] See R. Exs. OO-ZZ, LLL. (The TSC 1 [TSC = TS complex] gene is on chromosome 9q34. The TSC 2 gene is on chromosome 16p13. R. Ex. LLL; van Slegtenhorst, M., et al., "Identification of the Tuberous Sclerosis Gene TSC 1 on Chromosome 9q34," 277 Science 805-08 (1997). The authors state "TSC can be a devastating condition as the cortical tubers frequently cause epilepsy, mental retardation, autism, or attention deficit-hyperactive disorder, or a combination of these conditions." Id. at 805.)

When asked if a child who seized within three days of DPT would have a change in outcome, Dr Osborne answered he could not say it definitely would, but it might and occasionally does (however, not more likely than not). Tr. at 631-32. Dr. Osborne testified that he has never said that DPT was the probable or likely cause of a seizure in a TS child, but he has said it was a possible cause. Tr. at 645. The effect of DPT might be as overwhelming in a child with one tuber as with many. Tr. at 666.

Dr. Marcel Kinsbourne, a pediatric neurologist, testified next for petitioners. Tr. at 674. It is unquestionable that the number of tubers is a risk factor for outcome in TS. Tr. at 687-88. He does not believe that the TS does the damage itself. Tr. at 694-95. Something else decides when the seizures begin. Tr. at 695. Tubers mean there is an electrical difference between the tuber and the normal brain. Tr. at 705-06. There is no evidence that TS predetermines the outcome because the outcome in TS patients ranges so widely. Tr. at 709. Biological processes are continuous. Tr. at 711. The younger a child is, the greater the risk. Id.

Dr. Kinsbourne thought the number of cases included in Dr. Lamm's reevaluation of the Bellman 1983 paper was too small to look for the unusual effect of DPT causing seizures in a TS child since it happens only occasionally. Tr. at 725. TS causes twenty percent of all cases of infantile spasms: Tr. at 726. In Bellman's use of the NCES data, he had 262 patients with infantile spasms. Id. Dr. Kinsbourne would expect that fifty of the infantile spasms cases would have TS, but there were only sixteen. Id. He thinks that DPT and a high cortical tuber count is worse than DPT and a low cortical tuber count. Tr. at 732. The 1983 Bellman paper had a limited point. Tr. at 762. You cannot use the NCES data as evidence against a DPT recruitment effect on TS patients. Tr. at 763.

Dr. Kinsbourne agreed that cortical tuber count is a strong predictive factor of having seizures, including infantile spasms, and that it is more likely that a TS child will have infantile spasms. Tr. at 792. He did think it incoherent to say that TS alone

causes a bad outcome. Tr. at 793. He thinks that DPT is an infrequent cause of infantile spasms in a TS child, but the issue has not been formally studied.[34] Tr. at 798.

Dr. Kinsbourne is relying on the Decker twins[35] as the basis of his opinion that DPT causes infantile spasms in TS patients. Tr. at 8 15-16. He thinks that DPT is a contributory factor in only some, but not all, TS children. Tr. at 817. The incidence of neurologic reaction in TS and non-TS children should be the same, but the consequences are different. Tr. at 819. One cannot tell if DPT has a trigger or recruitment effect. Tr. at 819-20. He testified that the opinion that DPT is an occasional cause of infantile spasms is a minority view. Tr. at 827-28.

In 1994, the IOM issued a reevaluation of the NCES conclusions, based on a follow-up ten years later: "DPT Vaccine and Chronic Nervous System Dysfunction. A New Analysis," (National Academy Press, 1994). P. Ex. 82A. Positing the theory that DPT could trigger acute neurologic signs and symptoms in children with underlying brain or metabolic abnormalities, the IOM entertained that vaccinees who had serious, acute neurologic illnesses after DPT might go on to have chronic nervous system dysfunction. Id. at 13-14. However, if that theory were true, DPT would not increase the overall or lifetime risk of chronic nervous system dysfunction because they would eventually have reacted in the same fashion to another type of acute illness. Id. at 14. Another theory the IOM posited is that children with underlying brain or metabolic abnormalities might eventually develop chronic nervous system dysfunction even without an acute neurologic illness. The IOM called this theory the "provocative challenge unmasking the underlying abnormality." Id. But in this

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[34]Dr. Kinsbourne's testimony in October 1996 was before the Jozwiak paper was written and only the abstract (one paragraph) was in evidence. Dr. Kinsbourne testified again in June 1997 after the Jozwiak paper was produced.

[35]Destry and Damien Decker were part of Dr. Gomez's study of two sets of twins with TS. P. Ex. 57. The Deckers had DPT before the onset of their infantile spasms. Destry has 17 tubers, while Damien has 23 tubers.

scenario, the IOM would not consider the relationship between DPT causal (unlike in the triggering scenario). Id. (The IOM also concluded causation if DPT caused a serious acute neurologic illness and subsequent chronic nervous system dysfunction in a child who seemed to have no underlying disorder. Id.)

The IOM said the NCES data do not permit distinguishing among the above three scenarios. Id. at 13-14. In the trigger scenario, the IOM would not posit cause of the chronic dysfunction. Id. at 15. Overall, the IOM states that the NCES data does not permit a conclusion of causation although their theorizing posits its plausibility in some cases. Id.

This court, in a case arising under a causation in fact analysis, has held that there is no difference between "trigger" and "cause." McMurry v. Secretary, HHS, No. 95-682V, 1997 WL 402407 (Fed. Cl. Spec. Mstr. June 27, 1997). That case did not concern a TS child, but one who without any apparent neurologic deficit experienced fever and seizures within a day of DPT vaccination. Since petitioners filed after the effective date of the new regulations, residual seizure disorder was no longer a Table injury.[36]

Since the IOM's 1994 report (P. Ex. 82A) does not deal specifically with TS, using its rather broad theories of relationship is limited at best. The court accepts, per Drs. Gomez's,Osborne's, and Kinsbourne's testimony, that the earlier a TS child seizes, the worse his or her condition will be. Dr. Gomez's 1995 article with Drs. Shepherd and Houser states as much. R. Ex. 0. Considering that there are a whole host of possibilities for underlying neurologic abnormalities, the court cannot comfortably rely upon the IOM's 1994 report as proof of causal relationship in this case, particularly in light of the highly-specific evidence of both clinical neurology and medical literature concerning TS.

Petitioners also submitted P. Ex. 54, Shepherd, C.W., Beard, C.M., Gomez, M.R., Kurland, L.T., and Whisnant, J.P.,

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[36] See supra, note5.

"Tuberous Sclerosis Complex in Olmsted County, Minnesota, 1950-1989," 48 Arch Neur 400-01 (April 1991). There were 12 patients in the study. Id. at 400. One had an intellectual disability and seven had seizures. Id. at 401. With this small number, estimation in general of the number of TS patients with intellectual disability is precarious. Id.

P. Ex. 55, Osborne, J.P., Fryer, A., and Webb, D., "Epidemiology of Tuberous Sclerosis," 615 Annals of the New York Academy of Sciences, 125-27 (April 1991), recounts that the only study of any size to report the frequency of mental retardation in TS individuals was one from Oxford in 1984 which reported 68 percent had mild or severe retardation. Id. at 125. Osborne and his co-authors studied 2,830,921 individuals and found 83 TS people. Id. at 126. Of these, 52.5 percent were mentally retarded. Id. Eighty percent of the affected people had seizures, which meant that 27.5 percent of individuals with seizures had normal intelligence. Id. (P. Ex. 62 is the same as P. Ex. 55.)

P. Ex. 58, Clarke, A., Cook, P., and Osborne, J.P., "Cranial Computed Tomographic Findings in Tuberous Sclerosis are not Affected by Sex," 36 Develop Med and Child Neur 139-145 (1996), found that more males than females with TS had learning disorders, and that high tuber count did not sufficiently explain the difference. Id. at 142. The authors speculated that males may be more sensitive to seizures and especially to infantile spasms. Id. at 144. (Jozwiak, however, found no higher risk factor for mental retardation among males than among females with TS. R Ex. EEE at 2,12, 15.)

In P. Ex. 59, Webb, D.W., Fryer, A.E., and Osborne, J.P., "Morbidity Associated with Tuberous Sclerosis: A Population Study," 38 Develop Med and Child Neur 146-55 (1996), the authors studied age of onset of seizures in 131 TS patients. Id. at 147. Seizures occurred in 102 of them (78 percent). Id. Age of onset was known in 99 cases and it was under one year for 70 of them (69 percent) with a peak between three and six months. Id. The peak age for infantile spasms was four months and 70 percent

occurred between three and seven months. Id. In males, 33 percent had infantile spasms; in females, 18 percent. Id. In males, 22 percent had partial seizures, episodes of absence and tonic-clonic seizures; in females, 31 percent. Id. Seven patients had febrile convulsions as their first seizure, and two patients had myoclonic seizures. Id. at 147-48. Six had episodes of status epilepticus. Id. at 148. Seventy patients (53 percent) had a learning disorder; all of them had a history of seizures, but not all patients with seizures had a learning disorder. Id. at 148. The authors state that individuals with TS have an increased risk of seizures throughout life. Id. at 152.

P. Ex. 64, Osborne, J.P. and Fryer, A.E., "Tuberous sclerosis (epiloia, Bourneville's disease)," 2 Clinical Neurology 1526-32 (Swash and Oxbury, eds., 1991), states that the majority of TS patients have seizures. Id. at 1526. Most series report seizures in excess of 85 percent of TS cases, occurring usually in early life, with up to 50 percent of them having infantile spasms. Id. Many types of seizures occur in TS. Id. The role of DPT immunization in initiating seizures is unclear. Id. Citing the Hunt 1983 paper (R. Ex. K), Drs. Osborne and Fryer state that "there is no good supportive scientific evidence" to regard DPT as the trigger of TS children's problems. Id.

P. Ex. 66, Fryer, AL., Chalmers, A.H., and Osborne, J.P., "The value of investigation for genetic counseling in tuberous sclerosis," 27 J Med Genet 2 17-23 (1990) describes TS as "best known for causing mental retardation and fits...." Id. at 217.

At the court's insistence, Dr. Manuel Gomez testified on June 3, 1997, after the writing and filing of the Jozwiak paper. Tr. at 1392. Since his testimony in 1991, Dr. Gomez's opinion (communicated through letter form to respondent[37]) appeared to be changing concerning DPT as a trigger of seizures in TS children. Since Dr. Gomez is the world's expert on TS, the court found it crucial to ask him what his opinion was, whether it had

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[37]See R. Ex. N.

changed, and why.

In the Hanlon case, Dr. Gomez, after reviewing the records, opined that the cause of Michael Hanlon's seizure onset was the cortical lesions of his brain. Tr. at 1397. He stated that DPT did not significantly aggravate his seizure onset, and that Michael's current condition is due to his TS. Id. DPT was not a catalytic factor in this case. Tr. at 1398-99. One can determine the location of the tubers by the symptoms in the child. Tr. at 1400. For instance, Damien Decker has tubers in his left temporal lobe, a site that is correlated with autism (a condition that Damien has). Tr. at 1401.

In the Plavin case, Dr. Gomez testified that the cause of Rachel Plavin's seizures is her cortical lesions. Tr. at 1408. TS is manifested by seizures. Tr. at 1409. Recently, surgery has been done where if one removes the tuber, the seizure stops. Id. Literature describing seizure onset in twins indicates that they have infantile spasms at approximately the same time. Tr. at 1419.

Respondent's Exs. HH, I, JJ, and KK are studies on infantile spasms in monozygotic twins (the Deckers are monozygotic twins). Respondent produced these studies as proof that onset of seizures in twins occurs closely in time without a preceding DPT vaccination.

In Pavone, L., Mollica, F., Incorpora, G., and Pampiglione, G., "Infantile spasms syndrome in monozygotic twins," 55 Arch Dis Childhood 870-72 (1980), the authors discuss the onset of infantile spasms in twins on the same day (a few hours apart) at age six months. R. Ex. HH at 870. The spasms occurred and recurred at intervals of several seconds with episodes of 15 to 20 spasms. Id. The authors state, "The precise mechanisms underlying the syndrome of infantile spasms are still unknown despite the fact that a variety of genetically-determined conditions (in particular tuberous sclerosis) have been described." Id. at 872. There was no "apparent external triggering factor. This would suggest some kind of 'preprogrammed' type of disease." Id.

Pavone, L., Mollica, F., Incorpora, G., and Pampiglione, G., "Infantile spasms syndrome in monozygotic twins. A 7-year follow-up," 6 Italian J of Neur Science 503-06 (1985), continue discussing the same twins. R. Ex. II. They had received oral polio vaccine at the ages of three and four months. Id. at 503. At four months, they seemed to lag in motor and psychomotor development. Id. Their seizures at six months were initially viewed as colic. Id. at 503-04. Treatment was begun two months after onset. Id. at 505. One twin was first treated with Clonazepam and later given ACTH followed by Phenobarbital, and was attending normal school. Id. at 504. The other twin, who was first treated with ACTH followed by Prednisolone and Clonazepam, lagged his brother. Id. No cause was found for the infantile spasms. Id. at 505.

Segal, R.A., Chapman, C., and Barlow, J., "Monozygotic Twins with Seizures. Shared Characteristics," 48 Arch Neur 1041-45 (1991), discuss eleven sets of monozygotic twins with idiopathic seizure disorders. R. Ex. JJ. Three sets of twins had their onset of clinical seizures within one day of each other. Id. at 1041. The concordance of the clinical seizure pattern, the EEG patterns, "and, most strikingly, the timing of onset of the first clinical seizure implicate genetic determinants. " Id. The mean interval between the onset of seizures in co-twins was less than three months in the eight cases that could be analyzed. Id. In nine sets of twins, both twins had at least one seizure, a very high concordance rate of 82 percent. Id. at 1041, 1043. The actual concordance rate was probably higher because, in one of the two sets of twins in whom only one twin seized, the asymptomatic twin had an abnormal EEG, showing a propensity to seize. Id. at 1043. The authors state, "The most striking feature in this series of epileptic twins is the frequency with which the time of onset was shared by the twins." The twins who seized within a day of each other were afebrile, ruling out the possibility of a shared infection. Id. at 1044.

Fujiwara, I., Nakamura, H., Watanabe, M., Yagi. K., Seino, M., and Nakamura, H., "Clinicoelectrographic

Concordance Between Monozygotic Twins with Severe Myoclonic Epilepsy in Infancy," 31(3) Epilepsia 28 1-86 (1990), discuss monozygotic male twins whose seizure onsets were at ten months (Twin A) and eleven months (Twin B). R. Ex. KK at 281, 283. Fever precipitated Twin A's seizure, while immersion in hot water precipitated Twin B's seizure. Id. The twins had three different seizure types occurring in the same sequence. Id. at 285. The authors believed that genetic, rather than exogenous, factors were the cause of the seizures. Id.

Dr. Gomez testified that he is not sure that DPT causes seizures, but it could if there is an acute illness. Tr. at 1420. However, in the instance of infantile spasms, there is no evidence that DPT causes them. Id. As for Dr. Lamm's cortical tuber count paper (of which Dr. Gomez is the last named author), Dr. Gomez said one cannot be that precise on the number of tubers. Tr. at 1422, 1462. One cannot be so exact with biology; biology is not a mathematical science. Tr. at 1425. The location and size of tubers, besides their number, are very important, agreeing with Dr. Roach's editorial following the cortical tuber count published paper. Tr. at 1426, 1462-63. Tubers contain abnormal cells that fail to develop, mature, and migrate. Tr. at 1427. As far as those with eight or more tubers are concerned, some will seize and some will not. Tr. at 1433. One has to look at the specific case; one cannot generalize. Id.

Both Hanlon and Plavin did not have infantile spasms. Tr. at 1435-36. They had complex partial (focal) seizures. Tr. at 1436. Their seizures did not become generalized. Id. DPT can possibly cause afebrile seizures that are general. Tr. at 1441-43.

If an insult to the body were to cause infantile spasms, it would take a period of time (sometimes six-weeks, three months, six months or one year) between the time of the insult and the onset of seizures. Tr. at 1444. Dr. Gomez could not say that someone with eight tubers would be mentally retarded. Tr. at 1470. If someone had ten tubers, he would probably have seizures. Tr. at 1472. If someone had twenty tubers, he would surely have seizures. Id. The onset of seizures in the Decker

twins after DPT could be a coincidence. Tr. at 1473-74.

Dr. Peter Kellaway, an expert in electromyography with forty-five years' experience, never saw infantile spasms after a lesion or insult. Tr. at 1475. Dr. Kellaway wrote to another respondent's expert, Dr. Rita Lee, on October 7, 1996, stating that in more than forty-five years of clinical and research studies of infantile spasms involving several thousands of children referred for EEG, he and his associate never saw a case of infantile spasms "develop acutely in response to brain injury or acute disease." R. Trial Ex. N (Dr. Peter Kellaway and Dr. Richard A. Hrachovy).

Dr. Gomez testified that a child will be worse if his onset of infantile spasms is at three months rather than at eight months. Tr. at 1513. He stated that the Melchior study (R. Ex. H) disproves the Jeavons and Bower study.[38] (P. Doc. #4 attached to Dr. Kinsbourne's Response to the Government's Ten Question Supplementation Request, filed January 21, 1997; also filed separately by petitioners on September 23, 1996). Tr. at 1517-18.

The Jeavons and Bower 1964 study states that in nearly 70 percent of cases of infantile spasms, onset is within the first six months, and, in nearly 90 percent, within the first year of life. Jeavons and Bower at 11. Among factors in the symptomatic group is TS. Id. at 15. Jeavons and Bower discuss DPT as a factor and discuss literature showing DPT immunization before onset of spasms in 9 out of 24 children, but note there is other literature that views DPT as coincidental to onset. (In the pro-DPT-as-a-factor literature, 2 of those 24 children had onset of infantile spasms after smallpox vaccination.) Id.

In pursuing DPT vaccine as a causative factor, Jeavons and Bower focused on onset within one week of vaccination. Id. at 36. The authors believed immunization was a cause in some cases, admitting that individual case histories prove little. Id. at 37. They recommended a "very large scheme for collection of

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[38]Jeavons, P.M., and Bower, B.D., "Infantile Spasms. A Review of the Literature and Study of 112 Cases," 15 Clinics in Developmental Medicine 1-82 (1964) (hereinafter "Jeavons and Bower").

data to obtain statistical information to prove or disprove the theory." Id.

As if in answer to Jeavons' and Bower's suggestion, the NCES is the largest study of DPT and serious, acute neurological illness in association with DPT in the literature. P. Ex. 80A; supra, note 25. The authors did not exclude cases in which there was evidence of another possible cause, even though it might have the effect of overestimating risks. Id. at 141. They found no statistically significant risk in DT vaccine of severe convulsions or encephalopathy within seven days or 72 hours of vaccination, unlike their findings for DPT. Id.

The authors emphasized that their findings "suggest, but do not prove that immunization with DTP vaccine does cause the development of serious neurological disorders in a small number of children...." P. Ex. 80A at 143.

In Dr. Gomez's opinion, regardless of the age of onset, tubers cause the seizures in children who have TS. Tr. at 1545.

Also testifying in June 1997 was Dr. Kinsbourne, in response to Dr. Gomez. Tr. at 1649. Crucial to his opinion of a relationship between DPT and seizures in a TS child are the dates of vaccination and onset of seizures. Tr. at 1650. He stated that the brain is not ready for infantile spasms until it is three months old. Tr. at 1653. He admitted that the opinion that DPT causes infantile spasms is a minority view. Tr. at 1678.

In criticism of Dr. Melchior's conclusions (R. Ex. H), Dr. Kinsbourne stated that the two cohorts of vaccinated and unvaccinated by the third month showed more children who were vaccinated had infantile spasms earlier. Tr. at 1693-94. Melchior went out to 18 months in forming his conclusion that there was no difference in onset of infantile spasms whether a child was vaccinated under the old series or new series of vaccine administrations. Tr. at 1694-95. If one compares the whole of the two groups, there is no difference in onset of infantile spasms between those vaccinated and those unvaccinated. Tr. at 1695. But the early months show a difference. Tr. at 1696. Dr. Kinsbourne stated that Dr. Melchior did a conservative test

showing all vaccinees, whereas he is less conservative (comparing early vaccinated with unvaccinated). Tr. at 1701. In Melchior's Table 1 (R. Ex. H, at p. 134), before the age of three months, 10 children in the 1957-67 series (unimmunized) and 25 children in the 1970-75 series (immunized two times, once at 5 weeks and once at 9 weeks) had onset of infantile spasms. Id. Melchior's Table 1 is as follows:

Table 1. Age at the first infantile spasms in two Danish series

	1957-67		1970-75	
Age(m)	n	%	n	%
<2	5	6	13	12
2	5	6	12	11
3	9	10	14	12
4	17	20	8	7
5	17	20	26	23
6	13	15	12	11
7	4	5	9	8
8	5	6	8	7
9-11	8	9	6	5
12-17	3	3	5	4
Total	86	100	113	100

There were, however, a total number of 86 in the 1957-67 series through the age of 18 months and a total number of 113 in the 1970-75 series through the age of 17 months. Id. However, Melchior's data do not show how many of the thirteen who had onset of infantile spasms before the age of two months in the 1970-75 series had their onset before the first vaccination at five weeks. Id. Moreover, since the testimony and the literature support an onset of infantile spasms most often in the window of time between three and eight months of life, one wonders how carefully the data depict the true nature of the seizures that occurred before three months and after eight months.

If we examine the data just for the window of time that had the most onsets of infantile spasms (four to six months), we come to a very different conclusion than Dr. Kinsbourne, one

consistent with Melchior's conclusion that pertussis vaccination had no effect on onset of infantile spasms. The total number of onsets between four months and six months in the 1957-67 series (vaccinated at five and six months), was 47 cases of infantile spasms; in the 1970-75 series (vaccinated at 5 and 9 weeks), there were 46 cases of infantile spasms. The numbers are practically identical. Thus, it appears that Dr. Kinsbourne's analysis that more vaccinated children in the younger (below three-month) group developed infantile spasms than in the series that was not vaccinated at that age is not a sufficient or persuasive analysis when one examines the greatest onset of infantile spasms in both vaccination groups.

Moreover, if we compare the number of onsets of infantile spasms from under two months of age to three months (39) with the number from four to six months (46) in the 1970-75 series, we see the number almost the same, yet the four to six months group had not been recently vaccinated.

If pertussis vaccine were the causative agent, one would expect that a greater number of onsets would occur in close proximity to receipt of the vaccine. But Melchior's data do not suggest this. In the 1957-67 series, pertussis vaccine was administered before the age of eight months (the terminus of onset of infantile spasms) at ages five and six months. Id. But the onset of infantile spasms among that group occurred just as often at age four months (17 cases) before vaccination as at ages five months (17 cases) and six months (13 cases) after vaccination. Id. Similarly, in the 1970-75 series, pertussis vaccine was administered before the age of eight months at ages five and nine weeks. But the onset of infantile spasms among that group occurred just as often at under two months (13 cases) which could have been before or after vaccination; at two months (12 cases) long after the first vaccination but before the second; three months (14 cases) long after the first and second vaccinations; at five months (26 cases), twice as many onsets and yet not in any time relationship to the first or second vaccinations; and at 6 months (12 cases), not in any time relationship to the first or

second vaccinations. Id. The Melchior data do not show any relationship between pertussis vaccination whether by comparing the two vaccination series (1957-67 and 1970-75) or by internally comparing onsets within each series.

In Dr. Kinsbourne's workshop with Dr. Menkes which, though published, is not a peer-reviewed article but a recounting of a discussion among pediatric neurologists of the effect of DPT, Drs. Kinsbourne and Menkes review the literature pertaining, in part, to DPT and infantile spasms. Tr. at 1697-98, P. Ex. 52. They cite Bellman, relying on the NCES data, that there is no positive evidence to link DPT and infantile spasms. P. Ex. 52 at 17,4. The relative risk of 2.46 for the onset of infantile spasms within one week of DPT immunization was not significant, especially when compared to a relative risk of 2.0 in DT immunized children. Id. They also cite Melchior's study and Fukuyama's study[39] for the proposition that DPT is unrelated to the onset of infantile spasms. Id. Dr. Kinsbourne thought, however, that one could conclude that DPT might cause the onset of infantile spasms in cryptogenic (unknown etiology) cases,

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[39]Fukuyania, T., Tomori, N., and Sugitate, M., "Critical Evaluation of the Role of Immunization as an Etiological Factor of Infantile Spasms," 8(3) Neuropadiatric 224-3 7 (1977). R. Ex. I. The authors took 110 cases of infantile spasms with information about immunization. Id. at 224. In 44 cases (40%), the children had not received vaccinations yet. Id. Another 44 cases (40%) had been immunized either one month before or after onset of infantile spasms. Id. They studied the remaining 22 cases and found age of onset of infantile spasms ranged from 3 to 9 months, with peak occurrence at 4-5 months, exactly identical to patients with infantile spasms in general. Id. The vaccinations they received were DPT (15 cases), smallpox (4 cases), polio (1 case), encephalitis (2). Id. By asking if there were no other causal factors, whether psychomotor development before onset was normal, and whether the interval from immunization to onset was within 48 hours of DPT or 18 days of smallpox, encephalitis, or polio vaccines, they found only 8 "compatible" cases (4.8%) and 2 "probable" cases (1.8%) fulfilling these criteria. Id. at 228-29,235. The authors concluded that the occurrence of 5 compatible cases out of 110 cases was easily explained by coincidence since the onset of infantile spasms occurs at the same time as immunizations within the first year of life. Id. at 235. R. Ex. J is the Institute of Medicine (IOM) chapter 4 from Adverse Effects of Pertussis and Rubella Vaccines (National Academy Press, 1991), which did a literature search and found no causation between DPT and infantile spasms. R. Ex. J at 77.

although this is unproven.[40] Id.

Dr. Shanna Swan, who is a Ph.D., not an M.D., testified about the Jozwiak paper to the effect that she did not think that one could conclude from it that DPT does not cause seizures such as infantile spasms in TS children because one cannot prove a negative. Tr. at 1706-07, 1716. She admitted that there was no statistically significant association between DPT and the onset of seizures in these children, but she thought that the field of epidemiology might move away from the standard of requiring statistical significance and be satisfied with less certainty. Tr. at 1717-19, 1739-40. The court was not impressed with Dr. Swan's testimony.[41]

In attempting to buttress its epidemiologic defense (Dr. Lamm's meta-analysis), respondent called witnesses to testify in the October 1996 portion in particular about Michael Hanlon and Rachel Plavin. The first of these witnesses was Dr. Robert. L. Zimmerman, a pediatric neuroradiologist. Tr. at 840. He testified that Michael Hanlon had ten cortical tubers. Tr. at 893.

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[40]Petitioners later submitted P. Ex. 77 as an article upon which Dr. Kinsbourne relied in his testimony: Riikonen, R., and Dormer, M., "Incidence and Aetiology of Infantile Spasms from 1960 to 1976: a Population Study in Finland," 21 Develop Med and Child Neur 333-43 (1979). Petitioners indicate that the mention of one case of infantile spasms occurring after febrile gastroenteritis (id. at 337) proves that an acute insult (the febrile gastroenteritis) can cause infantile spasms. Ergo, DPT, another acute insult, can also cause them. This conclusion is too facile for the court. One case out of 107 children of infantile spasms occurring after an infection that includes fever hardly proves that DPT, especially when a child is afebrile and not clinically ill, causes infantile spasms.

[41]According to Daubert v. Merrell Dow Pharmaceuticals Inc., 509 U.S. 579 (1993) (discussing admissibility of scientific evidence), "'general acceptance' can be an important factor...." The court must focus on "the principles and methodology." Id. at 594-95. By espousing minority views as to statistical certainty or causation of infantile spasms, Drs. Swann's and Kinsbourne's testimony, though admissible under the broad directives of the Vaccine Program (which does not adhere to the Federal Rules of Civil Procedure), is not as credible as the testimony of Drs. Lamm, Gomez, and Osborne, who are in the mainstream in accepting statistical significance as the appropriate standard or in opining that DPT does not cause afebrile seizures such as infantile spasms.

Dr. Rita Lee, a pediatric neurologist, testified for respondent. Tr. at 919. Tuber count is a very important, but not the only, factor in prognosing a child's ultimate outcome and likelihood of seizures. Tr. at 928. In a seizure, the neurons discharge abnormally. Id. A cortical tuber is a group of abnormal neurons. Tr. at 929. Neurons are brain cells that transmit messages. Id. The area around the tuber edge is decreased in myelination. Tr. at 930. It has an increase in fibrillary material. Id. The tuber or the area immediately adjacent to the tuber is the origin of the seizures. Tr. at 931. One can see a correlation on EEG between the discharges and the cortical tubers, although not always. Tr. at 931-32.

Dr. Lee testified that TS is a neuronal migrational disease. Tr. at 932. Precursor neurons begin their lives-just around the ventricles. Id. They migrate radially to the cortex. Tr. at 933. In TS, some cells do not get to the brain surface. Id. A tuber will not conduct normally. Tr. at 933-34. Bad outcome is accepted as a consequence of neuronal migration disorder. Tr. at 935. Dr. Lee referred to R. Exs. DD (Bebin article)[42] and EE (Palmini article)[43] as literature in support of the strong correlation between EEG results and large tubers. Tr. at 935-36. She also referred to R. Ex. G (Chugani article)[44] which recorded lesions on PET scan. Tr. at 937. The seizures stopped when the lesions were excised. Id.

The Bebin article, of which Dr. Gomez is a co-author, states "Seizures are the initial sign in 92% of patients with TSC [tuberous sclerosis complex]...." R. Ex. DD at 651. In all except one of the nine patients under study, EEG confirmed that seizure

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[42]Bebin, E.M., Kelly, P.J., and Gomez, M.R., "Surgical Treatment for Epilepsy in Cerebral Tuberous Sclerosis," 34 Epilepsia 65 1-57 (1993).

[43]Palmini, A., ~ "Focal Neuronal Migration Disorders and Intractable Partial Epilepsy: A Study of 30 Patients," 30 Ann Neur 741-49 (1991).

[44]Shields, W.D., Shewmon, D.A., Chugani, H.T., and Peacock, W.J., "Treatment of Infantile Spasms: Medical or Surgical?" 33 (Supp. 4) Epilepsia 526-531 (1992).

discharges came from a single region corresponding to a prominent neuroimaging sign on MRI. Id. at 652. After surgical excision of a primary focus lesion, six of the nine are now seizure-free, and the remaining two patients have decreased seizures. Id. at 656. The authors conclude that removing the primary focus lesion can also eliminate or silence secondary epileptogenic activity. Id.

The Chugani article states that "[i]t is important to recognize that infantile spasms are a manifestation of an underlying brain disorder rather than a disease entity unto itself" R. Ex. G at 526. "The most important predictor of outcome is the underlying cause.... The probability of normal outcome for children with symptomatic infantile spasms is only about 5%...." Id. at 527.

Symptomatic means the underlying cause is known, e.g., TS. Id. The authors recount a patient with TS in 1987 who had infantile spasms which resolved for seven months when his primary focus lesion was resected. Id. at S29-S30. When he resumed his normal anti-convulsants, he remained seizure-free. Id. at S30. They treated by resection nine other patients with infantile spasms, and seven of them remained seizure-free three to six years after surgery. Id. at S30.

Dr. Lee stated that tubers cause seizures in TS. Tr. at 938. One can often identify the tubers that cause the seizures by MRI, PET scan, and EEG. Id. One can stop the seizures by surgically removing the lesions. Id. In Dr. Lee's opinion, one does not need a catalyst for a TS child to start seizing. Tr. at 939. The tubers are an adequate source of seizure initiation. Id. We do not know the timing of seizures. Tr. at 939-40. Afebrile seizures are not due to DPT, although a febrile seizure might be (but not subsequent seizures in a TS child). Tr. at 940-41. She stated that it is possible for one to have afebrile seizures due to DPT, but it is rare. Tr. at 945. But Dr. Lee said she could not imagine how to prove that DPT causes infantile spasms because they do not occur as an acute response to an acute insult. Id. Infantile spasms take time to develop (at least three to four weeks). Tr. at 945-46. DPT does

not cause infantile spasms in close temporal proximity to vaccination. Tr. at 946. There is no evidence that DPT causes infantile spasms three to four weeks after immunization. Id.

TS causes all types of seizure except petit mal or juvenile absence seizures or benign Rolandic seizures. Tr. at 954-55. The consensus in the medical community is that DPT does not cause seizures other than acute, benign, febrile seizures. Tr. at 957-58. There is a high concordance between identical twins over whether and when they will develop epilepsy. Tr. at 962. Dr. Lee testified that infantile spasms are associated with a high tuber count. Tr. at 976. She stated that Michael Hanlon has TS, but DPT did not aggravate it. Jr. at 978. TS caused his first seizure. Tr. at 979. His current condition is not a sequela of his first seizure. Tr. at 980-81. He has ten cortical tubers, and he is better off than the majority of TS children she has cared for, although she does not know their tuber count. Tr. at 982-84. Michael Hanlon is not severely or moderately retarded. Tr. at 984. She thinks that Michael had infantile spasms, although he did not have hypsarrhythmia on EEG to confirm that. Tr. at 1003. He began with blinking spells. Tr. at 1008. By the age of six months, he had nodding spells. Id. That he had stiffening, kicking, jerking, and smiling at the end of a seizure without cyanosis or clonic movements suggests to Dr. Lee that he had infantile spasms. Tr. at 1008-09. Another respondent's expert,[45] however, stated that he had focal seizures, not infantile spasms, but Dr. Lee disagrees with him. Tr. at 1029-30. Even if Michael Hanlon had a different type of seizure than infantile spasms, her opinion about causation is the same. Tr. at 1055-56. TS children have seizures other than infantile spasms; it is common for them to have a mixed seizure disorder. Tr. at 1056.

Dr. Lee subscribes to the clock theory, i.e., seizures begin when there is a strong propensity without any sort of external factor prompting them. Tr. at 103 8-39. Besides the Melchior

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[45]Dr. Russell Snyder. R. Ex. A.

study-and Jozwiak study, common sense tells her that no added factor is necessary when one has a disease that disrupts brain function and structure. Tr. at 1040.

Dr. Lee relates Michael Hanlon's mental retardation to his TS, rather than to his seizures, where there are no long-term intractable seizures occurring right after each other as in prolonged status epilepticus.[46] Tr. at 1056-57.

Dr. Kinsbourne retook the witness stand to say that Michael Hanlon did not have infantile spasms clinically. Tr. at 1099. He agrees with Dr. Gomez that seizures unleash a dementing process. Tr. at 1119. Michael Hanlon eventually substantially deteriorated, but not right away. Tr. at 1142. Now he does not have seizures. Id.

Dr. Charles R. Fitz, a pediatric neuroradiologist, testified for respondent about Rachel Plavin's MRI.. Tr. at 1148. She has 43 tubers, some of which are unusually large. Tr. at 1152. She has one of the most severe TS cases he has examined. Id. Based on her 1990 MRI, between 20 to 30% of Rachel's cortex and subcortex are tubers. Tr. at 1168. He is sure that she has more than 43 tubers. Tr. at 1169. Rachel's MRI is in the top 5 of those he has reviewed as far as severity of disease. Tr. at 1171. The more tubers one has, the worse one is. Tr. at 1172.

Dr. Mary Ann Guggenheim, a pediatric neurologist, testified for respondent about Rachel Plavin. Tr. at 1175, 1194. DPT did not significantly aggravate her. TS. Tr. at 1196. There was chance temporal association, not causation, between DPT and her onset of seizures. Id. Since neither of Rachel's parents has TS, her TS is caused by a change in her DNA (chromosomes).

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[46] "[Children with tuberous sclerosis... all had high rates of mental retardation and intractable epilepsy." Riikonen, R., "Long-Term Outcome of West Syndrome: A Study of Adults with Infantile Spasms," 37(4) Epilepsia 367-72, 371 (1996). R. Ex. NN. See also, Roach, E.S., "Neurocutaneous Syndromes," 39(4) Ped Neur 59 1-620, 594 (1992). "Seizures occur in an estimated 80% to 90% of recognized patients [with TS] Infantile spasms are particularly common." Roach continues, at 595, to state that patients with severe cerebral disruption from TS (i.e., more tubers) are more likely to develop both intractable seizures and severe mental retardation. R. Ex. D.

Tr.
at 1196-97. There are at least two genetic loci established in TS. Tr. at 1197. When there is neuronal proliferation (cell division) and migration occurring, she had an error in the normal process, producing tubers. Id.

The underlying physiologic change for seizures is an increase in the degree and location of neuronal discharge. Tr. at 1198. There is an excessive amount of excitatory electrical activity. Tr. at 1198-99. Tubers contain cells that are electrically active. Tr. at 1200. Dr. Guggenheim knows of no aspect of biological plausibility or experience to require a contributing factor to cause a seizure in a TS child. Tr. at 1211-12. The clock determines where and when epileptogenic discharges occur. Tr. at 1212. A number of epileptic syndromes, such as febrile seizures, benign Rolandic epilepsy, and juvenile myoclonic epilepsy, have a predictable clock. Tr. at 1212-13.

DPT can cause local reactions, such as irritability, high-pitched crying, and also febrile seizures, hypotensive-hyporesponsive shock collapse, anaphylaxis, and rare cases of acute global encephalopathy. Tr. at 1224-25. It is biologically plausible for the structural and cellular changes in TS to account for all the damage in a TS child. Tr. at 1230. One does not need to recruit a second cause. Id.

Rachel Plavin's course was due to TS; it was not due to an acute encephalopathy but insidious, progressive, focal seizures. Tr. at 124546. A lot of her brain tissue is abnormal. Tr. at 1246. Rachel has a structural abnormality in her right cortex. Tr. at 1247. Hence, she had left focal seizures. Id. She also developed a left hemiparesis. Id. Even if DPT caused Rachel's first seizure, the rest of her seizures and outcome are due to TS. Tr. at 1248-49.

Dr. Kinsbourne testified in response to Dr. Guggenheim's testimony. Tr. at 1300. He stated that no known neurophysiology says masses in the brain have any particular effect on the way the brain works. Tr. at 1304. The brain is a network. Tr. at 1305. Different parts get into a particular pattern in firing; this pattern could occur around inert matter. Id.

DISCUSSION

Although early literature supported the hypothesis that DPT causes infantile spasms, later literature, including more extensive analysis, disputes this. The early articles depict an extraordinary number of onsets of infantile spasms after DPT (9 out of 24, or 37.5%). If DPT truly caused all that many cases of infantile spasms, then the number of children with infantile spasms should number in the hundreds of thousands, if not millions, considering that administration of DPT is universal in this country.

Other analyses belie these statistics. Firstly, the NCES and the 1983 Bellman study both used the same data. They both found that the incidence of onset of infantile spasms after DPT and after DT was increased. But the NCES found that, overall, the risk of serious, acute neurological illness after DPT was statistically significant (which included more than infantile spasms, e.g., encephalopathy) but found that the risk of serious, acute neurological illness after DT was not statistically significant. Since the incidence of infantile spasms was the same after each vaccination (DPT or DT), then the difference in statistical significance had to have arisen because of the incidence of other serious acute neuropathies, not infantile spasms, after DPT, which did not occur after DT.

The 1983 Bellman study opined about the possibility of trigger without analyzing how it is plausible that the same incidence of onset of infantile spasms could occur after DT as after DPT.

The whole literature, as well as the evidence presented in this court, has been to the effect that the pertussis element of DPT contains toxins (both endotoxin and exotoxin) which act upon some immature brains in a deleterious manner, causing seizure disorder, encephalopathy, etc. See P. Ex. 52, Menkes, J.H., and Kinsbourne, M., "Workshop on Neurologic Complications of Pertussis and Pertussis Vaccination," 21 Neuropediatrics 171-76

(1990), particularly its reference to the Cody article,[47] at 173, that neither seizures nor shock-like symptoms followed DT, unlike DPT.

Although Congress did not initially distinguish the type of Table injury after DT or DPT (it subsequently revised its Table in regulations effective March 10, 1995), this court has never heard a case in which DT was alleged to have caused a seizure disorder. If there is any credence to be attached to the theory of how pertussis vaccine acts as a toxin in a child (and the court has accepted this theory in one death case, Misenko v. Secretary, HITS, No. 92-0013V, 1995 WL 76 1436 (Fed. Cl. Spec. Mstr. Dec. 7, 1995)), then there can be no basis for assuming that DT (without the pertussis vaccine) causes seizure disorders. Yet, the results of the NCES data as reflected in the NCES analysis and the 1983 Bellman paper point to equivalency of "reaction." What seems more likely to the court is that these are statistical artifacts which, by themselves, have no statistical significance. (If they had statistical significance, then the mere fact of the onset of infantile spasms after DT would have elevated the risk of acute, serious neurological reaction to DT to the level of statistical significance.)

The fact that children who develop infantile spasms do so at the very ages they receive DPT vaccine has to mean that some will develop infantile spasms in close proximity to their vaccination. Although petitioners doubt the conclusion that Melchior reached in his Danish paper, the data led him to believe that altering the vaccine schedule did not change the age of onset of infantile spasms. Dr. Kinsbourne queried whether, in the first two months, there was a greater incidence of onset among vaccinees, but the court has shown through an analysis of the figures that the rate of onset of infantile spasms was constant

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[47] Cody, C.L., et al. "Nature and Rates of Adverse Reactions Associated with DTP and DT Immunizations in Infants and Children," 68(5) Pediatrics 650-60 (1981). P. Ex. 81. The authors did a prospective study for reactions after 784 DT and 15,752 DPT immunizations given to children 0 to 6 years of age. Id. at 650. No infant among over 16,500 vaccinees developed infantile spasms. Id. at 656.

during the period when most of the children had their onset whether or not the child could have had a DPT vaccination in a reasonable period of time before the onset. Since the same rate of onset occurred within each series of vaccinations (1957-67 and 1970-75), and within the same series (1970-75), one would be hard pressed to show that DPT vaccine had any causative role.

Dr. Osborne doubted that DPT causes infantile spasms. Dr. Gomez adopted the same opinion after reviewing the literature respondent provided to the court (including the Melchior study, and the twins studies). Moreover, Dr. Gomez, in his 1991 testimony and in his book and 1982 article, was maintaining the appropriately cautious stance of a practitioner in the field of TS. One wants to do everything possible to avoid a TS child's starting to seize. If DPT is any risk at all, a responsible doctor would not recommend it. But a court of law is not treating a diseased child; it is trying to ascertain probabilities as to causation, at least in a significant aggravation case in which respondent's burden is to prove that TS caused in fact the vaccinee's seizures.

Medical literature and anyone knowledgeable about TS grant that the most prevalent expression of the disease is a seizure disorder, most often, but not always, in the form of infantile spasms. Two studies, one by a psychologist, Ann Hunt, and the other by a doctor, S. Jozwiak, analyzed TS patients to determine if there was an increased incidence of onset of infantile spasms after receipt of DPT. Each author concluded that the evidence showed no increased incidence. Interestingly, Ms Hunt's data showed an increased incidence after DT, rather than DPT, going beyond the anomaly of equal occurrence after DPT and DT in the NCES and 1983 Bellman data. Although she opined, as did Bellman, as to the possibility of a trigger effect from DPT vaccine (as well as from a host of other factors, including fever and teething), these are pure speculations because the data do not support them.

It is particularly disturbing to the court that petitioners' attempt to maintain the presumption of causality from the DPT

vaccination rests upon Dr. Osborne's opinion that DPT does not cause afebrile seizures of any kind and Dr. Kinsbourne's opinion that DPT causes infantile spasms is a minority view. Dr. Gomez, in his 1991 testimony, opined that the literature had associated DPT and infantile spasms, but in light of his more thorough education in the literature (courtesy of respondent), he has changed his mind. The literature that petitioners provided that Dr. Osborne co-wrote specifies the lack of proof of a causal relationship of infantile spasms with DPT as well as the majority of TS patients' having seizures and mental retardation (although not all who seize are delayed).

The court is most impressed with the testimony of Drs. Gomez and Osborne. These men have devoted their professional lives to the study of TS. Dr. Gomez is a pediatric neurologist, whereas Dr. Osborne is a pediatrician. Not only because Dr. Gomez is regarded as the world's expert in TS, but also because of his training and experience, the court must regard his testimony as the more credible in the area. But he and Dr. Osborne do not differ in opinion. TS is the overwhelming cause of seizures in a child afflicted with the disease, unless he develops a fever or some other well-recognized reaction to a vaccination.

When faced with the choice of whether TS caused in fact an individual's seizure disorder so as to rebut the presumption that DPT vaccination is the cause, the court must choose the former over the latter in every case in which the vaccinee has no symptom other than the seizure. It begs credulity to link DPT to a seizure in a child who is not anorexic, insomniac, feverish, crying, moody, irritable, depressed, vegetative, or behaves in any other abnormal way that would lead a parent as well as a physician to assume the child was unwell. The child need not manifest all these symptoms, but in a case in which he does not manifest any of them, one could hardly be reasonable, not arbitrary, and not capricious to hold that TS, a disease known to produce seizures, and consequent mental retardation, autism, and developmental delay, is not the cause and that respondent has failed to rebut the presumption that DPT is the cause.

One may query why a child's seizure begins at a particular time (and, if right after a DPT vaccination, why that event is not suspect). The answer lies in the genetic sphere, one in which all the answers are not available. But, certainly the four twins articles strongly indicate that there is a programmed aspect to seizure onset.[48] These articles concerned monozygotic twins (just as the Decker twins with whom Dr. Gomez was so impressed in his 1982 article). Without any precipitating factor, they seized in close proximity to each other. No one knows how genes (and genetic diseases) set up timetables. But they obviously do.

Respondent has attempted to show by its biomarker study of cortical tubers that the greater number of tubers predicts a bad outcome (which is possible only through the development of a seizure disorder). While a large number of tubers is indeed a factor (one that Dr. Gomez mentioned in his 1991 testimony and to which all the witnesses agreed at the hearing), it is not the sole factor. As Dr. Osborne and Dr. Roach (in his editorial to the published cortical tuber count paper) as well as Drs. Shepherd, Houser, and Gomez in their 1995 paper, stated, other factors decisive in outcome are the tubers' size and location. We do not have all the answers yet. But, as Dr. Gomez said, biology is more than statistics. The court cannot make a statistical determination based solely on tuber count that a child would more likely than not have his current condition.

By looking at the TS children whose cases are before me, the court sees a child with 13 tubers who is vegetative, while one with 17 tubers is planning to attend college. And both have seizure disorders.

It is indeed sad as well as tragic to have a brain-damaged child. No one can be prepared for the heroic sacrifice that parents must make when their child has TS and then develops a seizure

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[48] "[I]nfantile spasms become apparent at a special stage of brain maturation." Riikonen, R., and Donner, M., "Incidence and Aetiology of Infantile Spasms from 1960 to 1976: a Population Study in Finland," 21 Develop Med and Child Neur 333.43, 333 (1979). P. Ex. 76.

disorder. And there are some TS children, i.e., Costa, Moon, who do have reactions to DPT, which start them seizing. But they had obvious medical difficulties related to the vaccine. No one expects a TS child to go into immediate status epilepticus (prolonged seizure) or even coma as his first sign of a seizure disorder. Where such an event occurs, the DPT vaccine is indeed the cause.

However, where a TS child receives DPT vaccine and remains perfectly normal (in temperature, eating, sleeping, affect, and activity) but has a seizure within three days, TS, not DPT, is the cause in fact of that seizure. This is so whether or not the initial seizure takes the form of an infantile spasm or some other type of afebrile seizure such as Michael Hanlon and Rachel Plavin had.

Under the principles that the U.S. Court of Appeals for the Federal Circuit laid out in Whitecotton v. Secretary. HHS, 81 F.3d 1099 (Fed. Cir. 1996), petitioners initially satisfied their burden of showing Table onset in those cases, such as Hanlon and Plavin, in which the court has ruled that onset of seizures occurred within Table time and their current condition is obviously worse than their pre-vaccination status. However, respondent has successfully rebutted that presumption by showing that TS caused in fact their initial seizure as well as their current condition. (Actually, if respondent had sought to prove solely that petitioners' current condition was due to TS, but that DPT caused the initial seizure, they would also succeed in rebutting the presumption of significant aggravation. But the court holds that respondent has proven not only that the vaccinees' current condition is due to their preexisting TS, but also, in cases in which a seizure is the only symptom, that TS is the cause in fact of that seizure.)

To satisfy their burden of proving causation in fact, respondent must offer "proof of a logical sequence of cause and effect [for] the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect." Grant v. Secretary, HHS, 956 F.2d 1144, 1148 (Fed.

Cir. 1992). Agarwsal v. Secretary. HHS, 33 Fed. Cl. 482, 487 (1995); see also Knudsen v. Secretary. HHS, 35 F.3d 543, 548 (Fed. Cir. 1994); Daubert v. Merrell Dow Pharmaceuticals. Inc., 509 U.S. 579 (1993).

Respondent has proven by a logical sequence of cause and effect that the presence of tubers in the cerebral cortex, which is the hallmark of TS, leads to seizures in the majority of TS patients. Moreover, most of those who have seizure disorders are also mentally retarded. The effect of numerous tubers, as well as their location and size, is a given. Not one witness disputes their importance. Moreover, the epidemiology that is available (the 1983 Hunt and 1997 Jozwiak papers) supports the view that DPT does not initiate seizures in TS patients. The studies on monozygotic twins strongly suggest that there is a programmed aspect (a biological clock) to the onset of seizures in children with infantile spasms. The apparent administration of vaccinations at the very peak of incidence of onset of infantile spasms creates the suspicion, but no more than that, of a relationship. The NCES data and the 1983 Bellman paper based on the same data show the same incidence of onset of infantile spasms following DPT and DT, the latter vaccination never being associated with seizures. The lack of statistical significance in this phenomenon accentuates its lack of importance in determining causation from DPT. That surgical resection of cortical lesions results in the alleviation permanently or for a time of seizures in afflicted individuals reinforces the conclusion that seizures are linked to brain lesions. Moreover, it makes sense ("a logical sequence of cause and effect") that brain cells that are disordered and form lesions play a role in abnormal firing of those cells, or in the cells that lie between the lesions and the normal cortex.

To apply these holdings to the Hanlon and Plavin cases in which this court has ruled that Hanlon and Plavin are entitled to compensation requires the court to reconsider its holdings.[49]

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[49]The court will issue orders in Hanlon and Plavin, as well as in any other TS case in which it has already decided the issue of entitlement.

Michael Hanlon had repetitive eye blinking occasionally between the ages of two and four months. Between the ages of four and six months, he had recurrent blinking of the eyes associated with some jerking of the head to the right. These episodes were unaccompanied by fever. He received DPT vaccinations when he was two, four, and six months of age. Petitioners alleged that onset occurred one day after the first DPT. In light of this court's above holdings, the onset of Michael's seizures was coincidental to his first DPT vaccination. By looking at the course of his seizures, one can see that they were happening without any reaction to an antigenic insult.

In Rachel Plavin's case, Rachel's parents stated that on the day of her second DPT vaccination, at the age of three and one-half months, she was staring, her left arm shook, and she drew her legs up. Eleven days later, she was brought to the hospital. The history the mother gave was that Rachel had been healthy until she noticed occasional trembling of her left hand while she nursed and one blank stare. The mother did not give an onset date. She did, however, state that Rachel did not have a reaction to her DPT vaccination ten days earlier. A subsequent history was that the onset was at approximately two months with a shaking left hand. By two and one-half months, these were apparently seizures. A history two weeks later was that the first seizure occurred on the day of the DPT vaccination while nursing. Rachel's left arm vibrated and she began shaking and staring.

Again, Rachel's symptoms seem to be totally unrelated to the DPT vaccination and purely coincidental. In her mother's mind, she was not having a DPT reaction. These symptoms are typical of a TS child's initial seizures. One should also note that Rachel has 43 or more cortical tubers, making up a substantial percentage of her cortex. Based on the court's above holdings, the onset of Rachel's seizures was coincidental to her second DPT vaccine.

CONCLUSION

Respondent has successfully rebutted petitioners' presumption of significant aggravation of preexisting TS from

DPT vaccine by proving that TS caused in fact both petitioners' onset of seizures and current condition in all cases in which the onset of seizures was unaccompanied by symptoms of a vaccine reaction, such as fever, anorexia, insomnia, depressed affect, shock, etc. The court will examine each case, even if already decided on the issue of entitlement, to determine if they fall into the category of Hanlon and Plavin, who are not entitled to compensation.

IT IS SO ORDERED.

DATED: September 15, 1997

s/
Special Master
Laura D. Millman

APPENDIX D: ORDER OF THE OFFICE OF SPECIAL MASTERS OF THE UNITED STATES COURT OF FEDERAL CLAIMS, DATED SEPTEMBER 18, 1997

UNPUBLISHED
In The United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 90-1334V
September 18, 1997

JOHN HANLON and RUTH ANNE HANLON, Parents and Next Friends of MICHAEL HANLON,

Petitioners,

vs.

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Respondent.

Richard Gage, Cheyenne, WY, for petitioners.
Karen P. Hewitt, Washington, DC, for respondent.

ORDER TO VACATE

MILLMAN, Special Master

On September 15, 1997, the court issued a decision in the Omnibus TS proceedings. Barnes. et at. v. Secretary. HHS, No. 92-0032V, 1997 WL _____ (Fed. Cl. Spec. Mstr. Sep.15, 1997). Pursuant to my holding in the TS Omnibus Decision, I vacate my decision of May 31,1994 that found petitioners entitled to an award.

This case is hereby dismissed with prejudice. In the absence of a motion for review filed pursuant to RCFC Appendix

J, the clerk of the court shall enter judgment accordingly.

IT IS SO ORDERED.

Date: September 18, 1997

s/
Laura D. Millman
Special Master

APPENDIX E: ORDER OF THE OFFICE OF SPECIAL MASTERS OF THE UNITED STATES COURT OF FEDERAL CLAIMS, DATED SEPTEMBER 18, 1997

UNPUBLISHED
In The Unites States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 91-1555V
September 18, 1997

MARC PLAVIN and TONI REISS, Parents and Next Friends of RACHEL LEAH REISS-PLAVIN,

Petitioners,

vs.

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Respondent.

Richard Gage, Cheyenne, WY, for petitioners.
Karen P. Hewitt, Washington, DC, for respondent.

ORDER TO VACATE

MILLMAN, Special Master

On September 15, 1997, the court issued a decision in the Omnibus TS proceedings. Barnes. et at. v. Secretary. HHS, No. 92-0032V, 1997 WL _____ (Fed. Cl. Spec. Mstr. Sep.15, 1997). Pursuant to my holding in the TS Omnibus Decision, I vacate my decision of December 29,1994 that found petitioners entitled to an award.

This case is hereby dismissed with prejudice. In the

absence of a motion for review filed pursuant to RCFC Appendix J, the clerk of the court shall enter judgment accordingly.

IT IS SO ORDERED.

Date: September 18, 1997

s/
Laura D. Millman
Special Master

APPENDIX F: OPINION AND ORDER OF THE UNITED STATES COURT OF FEDERAL CLAIMS, DATED MARCH 19, 1998

40 Fed. Cl. 609
In the United States Court of Federal Claims
No. 91-1555 V
(FILED: March 19, 1998)

MARC PLAVIN and TONI REISS, Parents and Next Friends of RACHEL LEAH REISS-PLAVIN,

Petitioners,

v.

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Respondent.

Robert T. Moxley and Richard Gage, Cheyenne, Wyoming, for petitioners.
Mary Hampton Mason and Karen P. Hewitt, Washington, D.C., for respondent, with whom were Assistant Attorney General Frank W. Hunger, Director Helene M. Goldberg, Deputy Director John Lodge Euler, and Assistant Director Gerard W. Fischer

ORDER

TIDWELL, Judge:

This case is before the court on petitioners' motion for review[1] of the September 18, 1997 decision of Special Master Millman denying compensation under the National Childhood Vaccine Injury Act ("Vaccine Act"), 42 U.S.C. §§ 300aa-1 - 34 (1994). *See Plavin v. Secretary of HHS,* No. 91-1555V (Fed. Cl. Sp. Mstr. Sept. 18, 1997) (dismissal order). In denying the petition for compensation, the special master adopted the

[1] In referring to petitioners' motion for review, the court is also referring to the accompanying memorandum of objections.

reasoning of her "TS Omnibus Decision," captioned in 22 cases, including this case. *Id.* (adopting *Barnes, et al. v. Secretary of HHS*, slip op. (Fed. Cl. Sp. Mstr. Sept. 15, 1997, as amended Sept. 18, 1997) (hereinafter "TS Omnibus Decision")[2]). For the reasons set forth below, the court grants in part and denies in part petitioners' motion for review. In doing so, the court reverses in part, affirms in part, and remands the special master's denial of entitlement to compensation in *Plavin*.

BACKGROUND

On behalf of Rachel Leah Reiss-Plavin ("Rachel"), petitioners filed a petition on October 30, 1991 for compensation under the Vaccine Act. Rachel was born on June 8, 1989, in Lexington Kentucky. Rachel received her first Diphtheria-Pertussis-Tetanus ("DPT") vaccination on August 4, 1989 at the age of two months. She received her second DPT vaccination on September 15, 1989, when she was three and a half months old. Rachel's parents allege that later that day, Rachel was staring, her left arm shook and she drew her legs up.

On September 26, 1989, Rachel was brought to Humana Hospital. Dr. Jacqueline Campbell noted that Rachel had been healthy until her mother noticed occasional trembling of her left hand while she nursed, along with one blank stare. Dr. Campbell concluded that Rachel was suffering from a seizure disorder, and in her summary mentioned Rachel's second DPT vaccination, given 10 days before admission to the hospital, and that Rachel had had "no reaction" to it.

In November 1989, Rachel was diagnosed with Tuberous Sclerosis ("TS"), a neurocutaneous genetic disorder affecting the skin and nervous system. TS causes lesions to appear on some organs, including the brain. One type of lesion, located on the cortex of the brain and called a "cortical tuber," is responsible for seizures, although not all TS patients with tubers have seizures.

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[2]The court's page references to the TS Omnibus Decision will refer to the version issued by the special master on September 15, 1997, as amended September 18, 1997.

Other symptoms of TS include mental retardation.

Also in November, 1989, Dr. Robert J. Baumann, a pediatric neurologist at the University of Kentucky Chandler Medical Center, indicated in his records that at two months of age, Rachel's mother noticed that Rachel had begun to have episodes where her left arm would shake, and by two and a half months of age it was apparent that these were seizures.

On December 12, 1989, Rachel was seen by Dr. Bryan C. Hall, the chief of the Division of Genetics and Dysmorphology and Professor of Pediatrics at the University of Kentucky. Dr. Hall recorded that Rachel had her first seizure on September 15, 1989, following a DPT vaccination. Dr. Hall stated that while Rachel was nursing, she pulled away from the nipple, and her left arm vibrated for a short period. She also began shaking and staring. A history given at the University of Kentucky Medical Center on November 1, 1990 records an onset of seizures at three and a half months.

Finally, on March 15, 1991, Dr. Campbell documented in a letter the sequence of events leading up to the diagnosis of Rachel's seizure disorder and TS. Dr. Campbell wrote that on September 15, 1989, Rachel's mother called her to discuss Rachel's fussiness, apparent abdominal cramping, and occasional brief arm tremor.

Presently, Rachel continues to suffer seizures and developmental delay, and she is approximately two years behind in gross and fine motor skills.

PROCEDURAL HISTORY

In their original petition, petitioners alleged that as a result of her second DPT vaccination, Rachel suffered significant aggravation of her pre-existing TS in the form of a residual seizure disorder ("RSD") within the Table time limits of the Vaccine Act. *See* 42 U.S.C. §§ 300aa-14(a)(I)(D) and (E). Respondent asserted that the onset of Rachel's seizure disorder occurred outside the Table time limits. In the alternative, respondent claimed that Rachel's seizure disorder was caused by a factor unrelated, Rachel's TS. No hearings were held, as the

special master found that the records were sufficient to make a determination. On December 29, 1994, the special master issued her decision granting compensation to petitioners on the grounds that Rachel had suffered an on-Table significant aggravation of her TS. *Plavin v. Secretary of HHS,* No. 91-1555V (Fed. Cl. Sp. Mstr. Dec. 29, 1994) (original entitlement order). In so deciding, the special master took into account prior TS/DPT decisions and the testimony elicited from them. *Id.*

Prior to the grant of entitlement to compensation in *Plavin,* two cases and the testimony of the world's acknowledged expert on TS, Dr. Manuel Gomez, had established a *per se* rule whereby when an on-Table significant aggravation was demonstrated in TS cases, entitlement to compensation was virtually automatic. This theory was premised on the testimony of Dr. Gomez, taken at the Mayo Clinic on October 21, 1991. Dr. Gomez's testimony was interpreted as stating that medically, DPT could be a "trigger" of seizures in TS children, and that based on that possibility he advised that his patients with TS should not receive the DPT vaccine. Dr. Gomez's fear was that the earlier onset of seizures in TS children resulted in an outcome worse than if the seizures, if they ever started, started later. At that time, Dr. Gomez did not discount the theory that the presence of cortical lesions on the brain of a TS child was also a factor involved in any resulting seizures and/or mental retardation.

The first case to apply that testimony was *Costa v. Secretary of HHS,* No. 90-1476V, 1992 WL 47334 (Cl. Ct. Sp. Mstr. Feb. 26, 1992) ("*Costa I*",) *vacated and remanded,* 26 Cl. Ct. 866 (1992) ("*Costa II*"), *on remand,* 1992 WL 365421 (Fed. Cl. Sp. Mstr. Nov. 5, 1992). In *Costa I,* the special master held that petitioners were entitled to an award of damages based on their proof of an on-Table RSD. On appeal to the Court of Federal Claims in *Costa II,* the court agreed that petitioners were entitled to compensation, but reversed the special master's basis for compensation of the vaccine injury as an on-Table RSD as a result of its finding that the case must be analyzed under the theory that the DPT vaccination had "significantly aggravated"

the vaccinee's TS. *See Costa,* 26 Cl. Ct. at 870-71. The court held that because TS is a pre-existing condition, analysis under the "significant aggravation" prong was necessary. *Id.* In addition, the court adopted the "triggering" theory advanced by Dr. Gomez in ordering entitlement for petitioners. *Id.* at 871. As a result of *Costa,* the remaining TS cases were analyzed solely under a theory of significant aggravation.

In addition, in *Suel v. Secretary of HHS,* No. 90-935V, 1993 WL 241430 (Fed. Cl. Sp. Mstr. June 18, 1993) *("Suel I"), rev'd and remanded,* 31 Fed. Cl. 1 (1993) *("Suel II"), on remand,* 1997 WL 617034 (Fed. Cl. Sp. Mstr. Sept. 22, 1997), the special master initially denied compensation based upon her finding that David Suel's eyes rolling back two days after his DPT vaccination, although a seizure, was not of sufficient severity to constitute a "substantial deterioration" under the Act's definition of "significant aggravation." Therefore, the special master held that although DPT was a trigger for David Suel's first seizure, it did not significantly aggravate his TS. The decision was appealed to the Court of Federal Claims, which reversed and remanded, holding that a *single* seizure in a previously asymptomatic TS child was *per se* significant aggravation of TS as a result of the vaccine "triggering" the TS. *Suel,* 31 Fed. Cl. at 11-12. In *Suel II,* as in *Costa II,* Dr. Gomez's "triggering" theory was explicitly adopted. *Id.* at 4-5, 9, 11-12.

Therefore, based upon *Costa* and *Suel,* and Dr. Gomez's testimony, the special master initially granted entitlement to compensation in *Plavin* on the grounds that Rachel's DPT vaccination had significantly aggravated her TS in the form of an on-Table partial focal afebrile seizure. *Plavin v. Secretary of HHS,* 91-1555V (Fed. Cl. Sp. Mstr. Dec. 29, 1994). On March 24, 1995, however, respondent filed a motion for reconsideration in light of a letter from Dr. Gomez, dated February 2, 1995 and sent to respondent, that indicated that Dr. Gomez was troubled with his initial testimony as recorded in the transcript and that there is actually no concrete evidence that supports the "triggering" theory. In addition, respondent alleged that additional new

evidence in a January, 1995 article highlighted that cerebral dysfunction in TS children, resulting in seizures and mental retardation, is primarily caused by the extent of the cortical tubers in a TS child's brain. Therefore, respondent requested that the special master reconsider her decision of whether it is more likely than not that the child's current condition is due to the significant aggravation of TS resulting from the vaccination or whether the condition is primarily due to TS alone.

Several TS cases had been decided prior to the apparent availability of the "new evidence." Subsequently, all of the TS cases were transferred to Special Master Millman, and on April 11, 1996, the special master issued an "Omnibus TS Order." The order stated that "[i]n order to resolve most efficiently all of [the TS] cases, the special master has undertaken an inquiry into the general medical and scientific issues surrounding TS and immunization, with the hope that knowledge and conclusions developed from this inquiry will apply to each individual case." *Barnes et al. v. Secretary of HHS,* 92-0032V (Fed. Cl. Sp. Mstr. Apr. 11, 1996). The special master held an Omnibus Hearing in two parts -- on October 8-11, 1996 and June 3-4, 1997 -- and particularly applied the testimony elicited from such hearings to *Plavin*, and also to *Hanlon v. Secretary of HHS,* 90-1334V (another case involving TS/DPT).[3] On September 15, 1997, the special master issued her TS Omnibus Decision, issued with the caption of *Barnes v. Secretary of HHS.* While the TS Omnibus Decision discussed Rachel's case and determined that she was not entitled to compensation based upon the findings therein, on September 18, 1997, the special master issued a separate order formally denying entitlement to compensation in *Plavin* based upon the TS Omnibus Decision. *Plavin v. Secretary of HHS,* No. 91-1555V (Fed. Cl. Sp. Mstr. Sept. 18, 1997). In the same order, the December 29, 1994 order finding petitioners entitled to

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[3]While the TS Omnibus Decision only applied the evidence elicited from the TS Omnibus Proceedings to the *Plavin* and *Hanlon* cases, the special master is subsequently applying such evidence to each TS case in the Vaccine Program.

compensation was vacated. *Id.*

On October 20, 1997, petitioners filed a motion for review of the special master's denial of compensation in *Plavin* after the Omnibus hearing. On November 20, 1997, respondent filed its response. In their motion for review and accompanying memorandum of objections, petitioners advanced three primary arguments. First, petitioners argue that the special master's "creation" of a "coincidence" theory of "factors unrelated" was arbitrary, capricious, contrary to the case law of TS vaccine compensation claims, and contrary to the terms of the Vaccine Act. Second, petitioners argue that the special master's reopening of the entitlement issues in the absence of newly discovered evidence was arbitrary, capricious and contrary to law. Finally, the petitioners state that the special master further abused her discretion and acted in a manner contrary to law by permitting the government, over petitioners' objection, to illegally contact, hire and co-opt the testimony of the petitioners' expert, Dr. Gomez. As the requested remedy, petitioners ask the court to reinstate the rule of *Suel* for Omnibus application in TS cases that fall under the Vaccine Injury Table. Therefore, petitioners request that the court reverse and remand this case to resume fact-finding and damages. In addition, petitioners request that the court order sanctions, "in the form of damages for delay caused by improper conduct contrary to the interests of justice."

In its memorandum in response to petitioners' motion for review, respondent asserts that the special master correctly applied the factors unrelated standard in her review of the Omnibus evidence, and that the special master's conclusion that Rachel's seizure onset and current condition is due to her TS is well supported by the record. Respondent also argues that the special master's reopening of the TS entitlement proceedings was not an abuse of discretion, and that petitioners' contentions about Dr. Gomez are specious.

DISCUSSION

As a result of the Omnibus approach utilized by the special master for this and several other TS/DPT cases, two

separate records, both relevant to the outcome in *Plavin,* have been created. There is a record relevant only to *Plavin*, and a record created during the Omnibus proceeding, which considered medical issues surrounding the general causal relationship, if any, between DPT, seizures, and TS. This court has been asked to review the September 18, 1997 denial of entitlement to compensation for Rachel Plavin. It is important to note that while this September 18, 1997 order adopted the reasoning of the TS Omnibus Decision, which specifically addressed Rachel's case, review of the factual and legal findings in the TS Omnibus Decision by this court will only be to the extent it applies to Rachel Plavin. This distinction is important in light of the parties' briefs, which largely addressed only the general findings in the TS Omnibus Decision that were intended to apply to all 22 cases captioned on that order.

The discussion below addresses the three arguments presented in petitioners' motion for review and accompanying memorandum of objections.

I. Standard of Review

In reviewing the special master's decision, findings, and conclusions, the court may (1) uphold the findings of fact and conclusions of law and sustain the decision, (2) set aside any findings of fact or conclusions of law found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law," or (3) remand the petition to the special master for further action in accordance with the court's direction. 42 U.S.C. §§ 300aa-12(e)(2); *see McCarren v. Secretary of HHS,* 1997 WL 801447 at 1-3 (1997) (clarifying that the standard of review is not *de novo*, but is the narrow "arbitrary and capricious" standard for both facts and law). The scope of review for this standard is exceedingly narrow; a court "may not substitute its own judgment for that of the special master if the special master has considered all relevant factors, and has made no clear error of judgment." *Costa,* 26 Cl. Ct. at 868 (quoting *Loe v. Secretary of HHS,* 22 Cl. Ct. 430, 432 (1991)).

II. The Special Master's Denial of Entitlement to Compensation in *Plavin*

A. Statutory Requirements and Burden of Proof

The Vaccine Act provides two principal avenues for a petitioner to seek compensation for injuries arising from the administration of a DPT vaccine. First, if a claimant suffers the first symptom or manifestation of an injury set forth on the Vaccine Injury Table ("Table"), 42 U.S.C. §§ 300aa-14(a), or if a claimant suffers the first symptom or manifestation of a significant aggravation of a pre-existing condition, within the time period designated on the Table, then causation is presumed. 42 U.S.C. §§ 300aa-11(c)(1)(C)(i). Significant aggravation is defined as "any change for the worse in a pre-existing condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." 42 U.S.C. §§ 300aa-33(4). The Act requires petitioner to demonstrate only that the symptoms, including a residual seizure disorder[4] or

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[4]An RSD occurs if:

> the petitioner did not suffer seizure or convulsion unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit before the first seizure or convulsion after the administration of the vaccine involved and if-- . . . (B) [in the case of a DPT vaccine], the first seizure or convulsions occurred within 3 days after administration of the vaccine and 2 or more seizures or convulsion occurred within 1 year after the administration of the vaccine which were unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit.

42 U.S.C. §§ 300aa-14(b)(2).

While RSD was removed from the Table effective March 10, 1995, *see* 42 C.F.R. §§ 100.1-100.3, Rachel's petition was brought in 1991 when RSD was still a "Table injury." *See* 42 U.S.C. §§ 300aa-14(a)(I)(D). Accordingly, Rachel's petition is considered under the "pre-change" Table. *See* 42 U.S.C. §§ 300aa-14(c)(4) ("[a]ny modification under paragraph (1) of the Vaccine Injury Table shall apply only with respect to petitions for compensation under the Program which are filed after the effective date of such regulation.").

encephalopathy,[5] were suffered within three days of the administration of the DPT vaccination. *See* 42 U.S.C. §§ 300aa-14(a)(I)(B), 300aa-14(a)(I)(D). In addition, even after it is determined that petitioner is entitled to a Table presumption, petitioner still must prove that any damage for which compensation is sought is in fact a sequela[6] of the Table injury. 42 U.S.C. §§ 300aa-14(a)(I)(E); *see also Song v. Secretary of HHS,* 31 Fed. Cl. 61, 65 (1994), *aff'd,* 41 F.3d 1520 (Fed. Cir. 1994).

As stated above, since *Costa,* TS cases have been analyzed under the "significant aggravation" theory. In *Whitecotton v. Secretary of HHS,* 81 F.3d 1099, 1107 (Fed. Cir. 1996), the Federal Circuit clarified the appropriate test to apply to determine if petitioners have met their burden of "significant aggravation" entitling them to the presumption of causation under the Act. *Whitecotton* articulated a four-part test to: (1) assess the person's condition prior to the administration of the vaccine; (2) assess the person's current condition; (3) determine if the person's current condition constitutes a "significant aggravation" of the person's condition prior to vaccination within the meaning of the statute; and, if so, (4) determine whether the first symptom or manifestation of the significant aggravation occurred within Table-time. *Id.*

The second avenue for compensation under the Act is more difficult. If manifestation or significant aggravation of an injury not listed on the Table occurs, or if a Table injury manifested itself outside the time period prescribed in the Table, then causation is not presumed and petitioner must prove *by a preponderance of the evidence* that the vaccine *actually caused* the injury. 42 U.S.C. §§ 300aa-11(c)(1)(C)(ii) (emphasis added); 42 U.S.C. §§ 300aa-13(a)(1)(A) (emphasis added).

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[5] "Encephalopathy" means "any significant acquired abnormality of, or injury to, or impairment of a function of the brain." 42 U.S.C. §§ 300aa-14(b)(3)(A).

[6] "Sequela" is defined as "an abnormal condition resulting from a previous disease." Random House College Dictionary 1201 (1st ed. 1982).

Once petitioners satisfy their burden of proving presumptive or actual causation, the burden shifts to respondent to demonstrate by *"a preponderance of the evidence* that the illness, disability, injury, condition, or death described in the petition [was] due to *factors unrelated* to the administration of the vaccine." 42 U.S.C. §§ 300aa-13(a)(1)(B) (emphasis added). The phrase "factors unrelated to the administration of the vaccine:"

(A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition, and

(B) may, as documented by the petitioners' evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioners' illness, disability, injury, condition, or death.
42 U.S.C. §§ 300aa-13(a)(2).

Therefore, in significant aggravation cases, once the petitioner has made a prima facie case, and therefore benefits from the statute's presumption of causation, the burden shifts to the government to show, by a preponderance of the evidence, that the pre-existing condition, was, in fact, the cause of the individual's post-vaccination significant aggravation. *Whitecotton,* 81 F.3d at 1107.

Respondent's proof of alternate causation in fact, that a "factor unrelated" caused the injury at issue, is subject to the same standards that apply to a petitioners' proof of actual causation in fact in off-Table cases. *Knudsen v. Secretary of HHS,* 35 F.3d 543, 549 (Fed. Cir. 1994). To satisfy the burden of proving the existence of the factor unrelated, and that this alleged condition actually caused the injury, respondent must prove a "logical sequence of cause and effect." *Id.* at 548 (citations omitted). This sequence "must be supported by a sound and reliable medical or scientific explanation." *Id.* (citing *Daubert v. Merrell Dow Pharms., Inc.,* 509 U.S. 579, 113 S.Ct. 2786, 2795-97 (1993)). In

addition, "[t]he determination of causation in fact under the Vaccine Act involves ascertaining whether a sequence of cause and effect is 'logical' and legally probable, not medically or scientifically certain." *Knudsen,* 35 F.3d at 548-49 (citations omitted). As stated in *Knudsen,*

> The Court of Federal Claims is . . . not to be seen as a vehicle for ascertaining precisely how and why DTP and other vaccines sometimes destroy the health and lives of certain children while safely immunizing others. This research is for scientists, engineers, and doctors working in hospitals, laboratories, medical institutes, pharmaceutical companies, and government agencies. The special masters are not "diagnosing" vaccine-related injuries. The sole issues for the special master are, based on the record evidence as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the child's injury or that the child's injury is a table injury, and whether it has not been shown by a preponderance of the evidence that a factor unrelated to the vaccine caused the child's injury.

Id. at 549 (citing 42 U.S.C. §§ 300aa-13(a)(1), (b)(1)). Therefore, "causation can be found in vaccine cases based on epidemiological evidence and the clinical picture regarding the particular child without detailed medical and scientific exposition on the biological mechanisms." *Knudsen,* 35 F.3d at 549 (citing *Jay v. Secretary of HHS,* 998 F.2d 979, 984 (Fed. Cir. 1993)).

B. Review of the Special Master's Omnibus Findings and Her Dismissal of *Plavin*

With the above standards and burdens as a backdrop, the special master in the Omnibus case undertook the colossal task of evaluating the evidence provided by the parties on the relationship, if any, between DPT, seizures and TS. As described

above, the purpose of the Omnibus proceedings was to consider the defenses presented by respondent in support of its "factor unrelated" defense. Respondent asserted, and attempted to prove through testimony and numerous written materials, that DPT does not cause infantile spasms or any afebrile seizures. Respondent also attempted to demonstrate that TS, and not DPT, is responsible for any seizures (including infantile spasms and other afebrile seizures) in a TS child if the child has eight or more cortical tubers.

Before issuing her TS Omnibus Decision, the special master heard testimony elicited through two hearings, as stated above, and reviewed countless articles submitted by the parties. The special master found in the TS Omnibus Decision that under the principles of *Whitecotton,* petitioners in Rachel's case "initially satisfied their burden of showing Table onset" under the significant aggravation theory as the court had previously found that "onset of seizures occurred within Table time and their current condition is obviously worse than their pre-vaccination status." TS Omnibus Decision at 64. The special master also held, however, that "respondent has successfully rebutted that presumption by showing that TS [as a "factor unrelated"] caused in fact the initial seizure as well as the current condition." *Id.* The special master based this conclusion on two general findings: (1) that DPT does not cause infantile spasms or the type of afebrile seizure that Rachel Plavin experienced; and (2) that absent other symptoms of a vaccine reaction, infantile spasms or afebrile seizures of the type that Rachel Plavin suffered is caused by a "factor unrelated," TS. In so holding, the special master determined that DPT does not "trigger" seizures in TS children. While the special master specifically discussed Rachel's case in the TS Omnibus Decision, she also subsequently issued an order on September 18, 1997 vacating the prior grant of entitlement to compensation in *Plavin* and denying entitlement based upon the findings in the TS Omnibus Decision. Therefore, a review of the denial of entitlement requires a review of the findings in the TS Omnibus Decision as those findings affect Rachel.

In their motion for review, petitioners ask the court to reinstate the *per se* rule of *Suel*, based upon their view that the special master's new rule articulated in the TS Omnibus Decision was arbitrary, capricious, an abuse of discretion and contrary to law. Petitioners advance numerous arguments in support of their contention that the TS Omnibus Decision should be reversed in its entirety.[7] Notably, petitioners argue that the TS Omnibus rule that requires proof of a "real vaccine reaction" imposes an improper causation in fact burden on petitioners. They state that an on-Table RSD, under the "pre-change" Table, is supposed to allow petitioners a presumption of causation. In addition, petitioners contend that in her ruling, the special master failed to hold the government to its burden of demonstrating actual alternative causation with its "factor unrelated" defense. Petitioners therefore contend that the grant of entitlement to Rachel Plavin prior to the TS Omnibus Decision should be reinstated. Respondent, on the other hand, stated that the "new" rule in TS/DPT cases is well-supported by the record created in the TS Omnibus Proceedings and should be upheld, and therefore that the denial of compensation to Rachel Plavin should be upheld.

1. TS Omnibus Finding That DPT Does Not Cause Afebrile Seizures

In the TS Omnibus Decision, the special master stated that the evidence presented during the Omnibus hearings supported respondent's assertion that DPT does not cause infantile spasms or any other afebrile seizures. The special master relied, among other evidence, on the opinions of Drs. Osborne and Gomez who doubted that DPT causes infantile spasms or partial afebrile seizures of the type Rachel suffered. The court does not question

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[7] As noted above, complicating the analysis is the omnibus approach taken in this case. Petitioners, in their motion for review, argued almost exclusively in general terms as to why the TS Omnibus Decision is faulty. As the court stated above, its review is limited to the affect of the TS Omnibus Decision on *Plavin*. Therefore, petitioners' arguments, while general, are interpreted solely in that light.

that significant evidence exists to support this theory, as presented during the Omnibus Proceedings and in other forums.[8] The court does question, however, the propriety of applying this evidence to petitioners' case that falls under the pre-change Table that presumes that DPT is the cause of the RSD if the first seizure occurs within 72 hours of the DPT vaccination. *See* 42 U.S.C. §§ 300aa-14(a)(I)(D) (1994) (containing the pre-change Vaccine Injury Table listing as a "Table injury" "[r]esidual seizure disorder[s]"). In their motion for review and at oral argument, petitioners argued that the special master's decision effectively repealed the relevant portions of the Vaccine Act granting a presumption of entitlement to compensation in TS cases when an on-Table RSD is demonstrated. Petitioners argue that in its general finding that DPT does not cause infantile spasms or the type of afebrile seizure that Rachel experienced, the special master imposed an improper actual causation burden on petitioner. Respondent argues that, to the contrary, the special master repeatedly stated that petitioners were entitled to the presumption of significant aggravation when an on-Table seizure was demonstrated. Respondent argues that *Knudsen* held that once a "factor unrelated" defense is asserted, evidence of whether immunization is in fact a possible cause of a petitioners' symptoms is relevant.

The court is concerned, as were petitioners, that in making the finding that DPT does not cause infantile spasms or the type of afebrile seizure that Rachel experienced on-Table, that petitioners' presumption of causation was diminished. The court does not disagree with respondent that after reviewing *all* of the facts and evidence in a particular case, a "factor unrelated" such as TS may be shown to be the cause of the seizures rather than the DPT reaction. This finding, however, cannot be based solely on

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[8]In fact, the court recognizes that the United States Department of Health and Human Services changed the Table, effective March 10, 1995, to remove RSD as a Table injury following DPT vaccination. *See supra,* note 3.

the special master's assertion that a type of seizure cannot be caused by DPT when the Act presumes that the opposite is so. Accordingly, because the court finds that the special master committed legal error in so finding, this narrow finding is reversed in *Plavin*.

2. TS Omnibus Finding That a Factor Unrelated, TS, Caused Rachel's Seizure

In support of their "factor unrelated" defense, respondent attempted to prove, in the Omnibus proceedings, that if a vaccinee has eight or more cortical tubers, seizures will inevitably develop and mental retardation will occur. Respondent presented evidence in support of this theory, including, among other evidence, an epidemiological "meta-analysis" by Dr. Steven H. Lamm, pediatrician and epidemiologist, of studies on the relationship between cortical tubers and the presence of seizures in TS children. The special master, however, refused to draw the line at eight tubers, noting in her Omnibus Opinion that "there is no clear-cut correlation between number of tubers and developmental delay" among the TS children presently in the Vaccine Program. She stated:

> While a large number of tubers is indeed a factor (one that Dr. Gomez mentioned in his 1991 testimony and to which all the witnesses agreed at the hearing), it is not the sole factor. As Dr. Osborne and Dr. Roach (in his editorial to the published cortical tuber count paper) as well as Drs. Shepherd, House, and Gomez in their 1995 paper, stated, other factors decisive in outcome are the tubers' size and location. We do not have all the answers yet. But, as Dr. Gomez said, biology is more than statistics. The court cannot make a statistical determination based solely on tuber count that a child would more likely than not have his current condition.
>
> By looking at the TS children whose cases are before me, the court sees a child with 13 tubers

> who is vegetative, while one with 17 tubers is planning to attend college. And both have seizure disorders.

TS Omnibus Decision at 63.

Instead of focusing on the number of tubers, the special master instead focused on the presence of the tubers and found that:

> Respondent has proven by a logical sequence of cause and effect that the presence of tubers in the cerebral cortex, which is the hallmark of TS, leads to seizures in the majority of TS patients. Moreover, most of those who have seizure disorders are also mentally retarded. The effect of numerous tubers, as well as their location and size, is a given. Not one witness disputes their importance.

Id. at 65. The special master cited, among other evidence, the studies on monozygotic twins that suggest that there is a programmed aspect to seizure onset, as well as the testimony that "surgical resection of cortical lesions results in the alleviation permanently or for a time of seizures in afflicted individuals" to show that seizures are linked to brain lesions. *Id.* In addition, the special master stated that "it makes sense ('a logical sequence of cause and effect') that brain cells that are disordered and form lesions play a role in abnormal firing of those cells, or in the cells that lie between the lesions and the normal cortex." *Id.*

As a result of the substantial evidence presented during the Omnibus proceeding, the special master, in her ruling, explicitly stated that in certain TS cases, TS rather than DPT, is the factor unrelated that causes on-Table seizures. The special master held:

> When faced with the choice of whether TS caused in fact an individual's seizure disorder so as to rebut the presumption that DPT vaccination is the cause, the court must choose the former over the latter *in every case in which the vaccinee has no*

> *symptom other than the seizure.* It begs credulity to link DPT to a seizure in a child who is not anorexic, insomniac, feverish, crying, moody, irritable, depressed, vegetative, or behaves in any other abnormal way that would lead a parent as well as a physician to assume the child was unwell. The child need not manifest all these symptoms, but in a case in which he does not manifest any of them, one could hardly be reasonable, not arbitrary, and not capricious to hold that TS, a disease known to produce seizures, and consequent mental retardation, autism, and developmental delay, is not the cause and that respondent has failed to rebut the presumption that DPT is the cause.

Id. at 62 (emphasis added). Later in the opinion, the special master again stated that TS, and not DPT, is the cause in fact of a seizure "when a TS child receives a DPT vaccine and remains perfectly normal (in temperature, eating, sleeping, affect and activity)." *Id.* at 63. She went on to say that "[t]his is so whether or not the initial seizure takes the form of an infantile spasm or some other type of afebrile seizure such as . . . Rachel Plavin had." *Id.* at 63-64.

In the Omnibus Decision, the special master applied her holding to Rachel's case, by referring to Rachel's parents' account of the initial seizure allegedly on the day of Rachel's second DPT shot, that Rachel was "staring, her left arm shook, and she drew her legs up." *Id.* at 66. In addition, the special master cited the hospital's account of Rachel's mother's history of Rachel's condition following the second DPT vaccination, in which she stated that "Rachel had been healthy until she noticed occasional trembling of her left hand while she nursed and one blank stare." *Id.* In addition, Rachel's mother did not give an onset date, but stated that Rachel did not have a reaction to her DPT vaccination ten days earlier. *Id.* The special master stated that subsequent histories of Rachel's condition characterized the

first seizure as occurring on the day of the DPT vaccination while nursing when "Rachel's left arm vibrated and she began shaking and staring." *Id.* The special master then held that "Rachel's symptoms seem to be totally unrelated to the DPT vaccination and purely coincidental." *Id.* The special master stated that "[i]n her mother's mind, she was not having a DPT reaction. These symptoms are typical of a TS child's initial seizures." *Id.* Then the special master added that "[o]ne should also note that Rachel has 43 or more cortical tubers, making up a substantial percentage of her cortex." *Id.* Finally, the special master stated that "[b]ased on the court's above holdings, the onset of Rachel's seizures was coincidental to her second DPT vaccine." *Id.*

To support her conclusion on Rachel, the special master relied on the testimony of Dr. Charles R. Fitz, a pediatric neurologist, who after studying Rachel's MRI stated that Rachel has at least 43 tubers, and that based on her 1990 MRI, between 20-30% of her cortex and subcortex are tubers. *Id.* at 56. In addition, the special master heavily relied upon the testimony of Dr. Gomez, who reviewed Rachel's medical records to come to the conclusion that "the cause of Rachel Plavin's seizures is her cortical lesions." *Id.* at 42, 61. In addition, the special master relied on the testimony of Dr. Mary Ann Guggenheim, a pediatric neurologist, to confirm that "Rachel Plavin's course was due to TS." *Id* at 57. In addition, the special master relied upon the record submitted in support of Rachel's petition.

In their motion for review, petitioners argue that the special master failed to hold respondent to proving that TS is indeed a "factor unrelated" and that it not only existed in Rachel's case, but that TS caused her on-Table seizure. The court finds both arguments to be invalid. First, the evidence more than adequately supports the special master's finding that TS fits the "factor unrelated" definition. TS is a well-established and explained disease with a known genetic origin unrelated to the administration of any vaccine. Although petitioner argues that TS does not fit the two-prong test enunciated in *Bernard v. HHS*, No. 90-2720V, slip op. (Fed. Cl. Jan. 30 1997), to determine whether

a disease can be a "factor unrelated," unlike Aicardi Syndrome, which was found in *Bernard* to be idiopathic, the two-prong test with respect to TS is satisfied in this case as the TS causing gene has been identified and evidence of the actual syndrome has been established. Even petitioners' expert, Dr. John Osborne, affirmed the special master's opinion that TS is a well-explained and non-idiopathic disease. As a result of all of the evidence elicited during the Omnibus proceedings, the special master's finding that TS can properly be a "factor unrelated" was not arbitrary, capricious or contrary to law.

Petitioners also argue that pursuant to the "factor unrelated" analysis in *Knudsen,* while respondent may have identified TS as a "factor unrelated," it did not actually prove that TS caused the injury. *See Knudsen,* 35 F.3d at 549 (requiring the government to prove that the factor unrelated not only exists but actually caused the Table injury complained of). This argument is also specious in light of the special master's more than adequate analysis of how the cortical tubers in TS patients cause seizures. *Knudsen* requires that the government prove that the factor unrelated was "principally responsible for causing the injury." *See Knudsen,* 35 F.3d at 550. The court is impressed with the weight of the evidence supporting the special master's finding that TS is, more likely than not, the cause, or the "factor unrelated" to the administration of the vaccine, of seizures in Rachels case, absent some other symptom or reaction to DPT. Respondents presented substantial evidence on how the lesions on a TS child's brain contribute to the child's seizure disorder. As described above, the special master's general analysis of the Omnibus testimony and evidence submitted is sound. In addition, both her Omnibus opinion and the record indicates that the special master went to great lengths to carefully apply the appropriate legal standards and burdens in this case.

However, while the weight of the evidence supports the special master's TS Omnibus Decision, the court remains concerned that in making her finding that Rachel's TS, as a factor unrelated, caused Rachel's on-Table seizure, the special master

relied upon her finding above that DPT does not generally cause infantile spasms or the type of afebrile seizures that Rachel suffered. Nowhere in her analysis is it clear whether the finding, that TS is the "factor unrelated" in *Plavin*, where allegedly no other vaccine reaction presented itself, can stand on its own absent the finding that DPT does not generally cause Rachel's type of afebrile seizure. Therefore, the court remands this part of the special master's decision in order for the special master to clarify whether her finding that TS is the "factor unrelated" that caused Rachel's on-Table seizure still stands absent the finding that DPT does not cause the type of afebrile seizure that Rachel experienced.

3. Whether "Other Symptoms" May Have Accompanied Rachel's Seizure

As stated above, the special master articulated a standard in TS cases whereby in instances in which a TS child suffers afebrile seizures within Table time allegedly as a result of a DPT vaccination, that TS, rather than the DPT vaccination, is the factor unrelated that actually caused the seizure *absent any other symptoms of a vaccine reaction.* Notably absent, however, from the record in the Omnibus proceedings is any indication that the special master considered evidence on the role of other *symptoms of a vaccine reaction* in TS/DPT cases, such as what those symptoms may be and how they may relate to either DPT vaccines or possibly to TS. And, of particular interest to this court, is whether Rachel Plavin actually had any other such symptoms, and if so, whether those symptoms can be causally related to the DPT vaccination from which petitioners alleged Rachel suffered a reaction. While the special master, in her TS Omnibus Decision, stated that "Rachel's symptoms seem to be totally unrelated to the DPT vaccination and purely coincidental," and that "these symptoms are typical of a TS child's initial seizures," absent from the record, the TS Omnibus Decision, and the subsequent order vacating the prior grant of entitlement to Rachel and dismissing the petition, is any evidence or discussion of whether Rachel's Table time injury included any "symptoms"

outside of the seizures that allegedly are "caused" by Rachel's TS. *See* TS Omnibus Decision at 66.

In support of its concerns, the court points the special master to a portion of Rachel's medical records encompassing a letter written on March 15, 1991, from Rachel's pediatrician, Dr. Jacqueline Campbell, documenting the events that led up to the diagnosis of seizure disorder and subsequently TS in Rachel. On the day of the second DPT vaccination, Dr. Campbell noted that Rachel's mother telephoned her to discuss:

> Rachels [sic] fussiness and apparent abdominal cramping. She also mentioned observing an occasional brief arm tremor without other symptoms.

Plavin v. Secretary of HHS, No. 91-1555V, Pet. for Vaccine Compensation, Medical R. at 289. While the court makes no findings as to whether the symptoms described above and in other portions of Rachel's medical records are indicative of an afebrile seizure or another type of vaccine reaction, it questions, for example, whether *fussiness* could be interpreted as a symptom of vaccine injury outside of the seizure allegedly caused by Rachel's TS. Therefore, the court remands to the special master in order to consider specifically whether Rachel Plavin had a "vaccine reaction" outside of her afebrile seizure. The court notes that petitioner mentioned during oral argument in this phase, and the record supports, that petitioners were not afforded a hearing as to Rachel's particular situation. While petitioners indicated they did not think such a hearing was necessary based on their arguments that the entire Omnibus opinion should be reversed, the court surmises that in the absence of such reversal, such a hearing would allow petitioners their opportunity to present any evidence, if available, that Rachel experienced any symptoms of a vaccine reaction outside of her seizure.

III. The Special Master Did Not Commit Reversible Error in Reopening the Proceedings on Entitlement

In their motion for review, the petitioners fault the special master's decision to reopen entitlement proceedings in *Plavin* and

in other TS cases in order to hear allegedly new evidence on the possibility that TS is the "factor unrelated" which caused the Table injury in TS cases. As stated above, on December 29, 1994, the special master issued her initial decision granting entitlement to petitioners in *Plavin*, as petitioners had satisfied their burden of showing Rachel having an on-Table onset of seizures which constituted a significant aggravation of her TS. The special master based her decision on Dr. Gomez's October 21, 1991 testimony that DPT may "trigger" the onset of seizures in TS children. *Plavin v. Secretary of HHS*, No. 91-1555V (Ct. Fed. Cl. Sp. Mstr. Dec. 29, 1994). Further support for her decision was based on the record submitted by petitioners, and on the report petitioners' expert, Dr. Kinsbourne, that Rachel's onset of seizures was on the same day of her second DPT vaccination. *Id.*

On March 24, 1995, respondent filed a motion for reconsideration of the December 29, 1994 grant of entitlement to compensation to petitioners in *Plavin* and in other TS cases. Respondent alleged that new evidence had surfaced which discounted the original testimony of Dr. Gomez on the "triggering" effect of DPT on TS children. Notably, respondent filed a letter from Dr. Gomez, dated February 2, 1995, that indicated that Dr. Gomez was troubled with his initial testimony and that there is actually no concrete evidence that supports this "triggering" theory. In addition, respondent cited an article published in January, 1995 that highlighted cerebral dysfunction, resulting in seizures and mental retardation, is primarily caused by the extent of the cortical tubers in a TS child's brain. Therefore, based on this evidence, respondent requested that the special master reopen the entitlement proceedings in all TS cases in which entitlement to compensation had been decided, in order to determine whether the original "triggering" theory was indeed accurate.

Petitioners objected to the reopening of entitlement. The special master, however, was interested in the new evidence and reasonably decided to reopen entitlement in all TS cases under the Vaccine Program, in an "Omnibus" fashion, in order to provide

an efficient forum to address the complex medical and scientific issues involved in all of the TS cases. The discussion above describes the nature and outcome of those proceedings.

In their motion for review, petitioners revisit this issue of reopening the proceedings in order to consider the new, and additional, evidence, supporting a "factor unrelated" case. Petitioners allege that at the time the entitlement proceedings were reopened, the evidence respondent proffered in support of the reopening was not "newly discovered," that the reopening itself was arbitrary, capricious and contrary to law, and that the reopening frustrated Congressional intent for the Vaccine Act to provide a "no-fault" remedy in a quick and inexpensive forum. Respondent argues that the special master in no way abused her discretion in hearing the Omnibus evidence in this case, because the reopening of the entitlement proceedings before a final judgment was entered was clearly within her discretion, particularly in the context of the flexible evidentiary rules of the Vaccine Program. Furthermore, respondent states the reopening was a result of the special master's correct interpretation of the situation as necessary to ensure fundamental fairness to both parties.

The court reviews the special master's rulings on evidence for abuse of discretion. *See Munn v. Secretary of HHS*, 970 F.2d 863, 870 n. 10 (Fed. Cir. 1992). Under the abuse of discretion standard, this court can only reverse for an error in interpreting law, or exercise of judgment on clearly erroneous findings of material fact, or irrational judgment in weighing relevant factors. *See, e.g., Chiu v. United States*, 948 F.2d 711, 713 (Fed. Cir. 1991) (citations omitted). Under the authority granted by 28 U.S.C. §§ 2071 (1994), and 42 U.S.C. §§ 300aa-12(d)(2), the Court of Federal Claims has promulgated rules of procedure for use by special masters.[9] These rules are governed by principles of

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[9]The Vaccine Rules of the Office of Special Masters are found in Appendix J of the Rules of the Court of Federal Claims (hereinafter "Vaccine Rules").

fundamental fairness to both parties. *See Dickerson v. Secretary of HHS,* 35 Fed. Cl. 593, 598 (1996). Overall, the Vaccine Rules accord the special master extensive discretion in conducting proceedings.

The record reveals that the special master acted well within her discretion in reopening the TS entitlement proceedings. The grant of entitlement in *Plavin* and in TS cases decided prior to it gave great weight to the 1991 testimony of Dr. Gomez that DPT could "trigger" the onset of seizures in children with TS. *See Costa,* 26 Cl. Ct. at 871; *see also Suel,* 31 Fed. Cl. at 4-5, 9, 11-12. In fact, that testimony led to the establishment of a per se grant of entitlement for TS children after it was established that the "significant aggravation" occurred within Table time. In light of the importance of Dr. Gomez's opinion on this matter, it was hardly an abuse of discretion for the special master to express interest in this new evidence. In addition, the article presented by respondents on the relationship between cortical tubers and seizures provided additional evidence that perhaps TS was the cause of the seizures. Accordingly, the court finds that the special master acted properly and did not abuse her discretion in reopening the proceedings based on this evidence.

In addition, the court agrees with the test promulgated by *Vant Erve v. Secretary of HHS,* 39 Fed. Cl. 607 (1997), which reversed a decision by a special master denying respondent's motion to reopen the issue of entitlement when new evidence had surfaced on the condition of the petitioner following a DPT.[10] While *Vant Erve* considered whether to reopen the entitlement proceedings in light of new medical information specific to the petitioner, and in *Plavin* the issue whether to reopen centered around general information on whether DPT "triggered" the onset

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[10]As noted by respondent in its Notice of Supplemental Authority, filed January 14, 1998, petitioners' reliance in its Motion for Review on Special Master Hastings' denial of respondent's motion to reopen the issue of entitlement was flouted by the Court of Federal Claims' reversal of that decision on November 21, 1997. *See Vant Erve,* 39 Fed. Cl. at 607, 616.

of seizures in TS children, both cases where in the same procedural posture, namely that the liability phase had ended, the special master had issued a ruling on entitlement, but a final judgment had not yet been entered. *See id.* at 612 (stating further that the standards of Federal Rule of Civil Procedure 60(b)(2) for relief from judgment did not directly apply at that procedural posture). Therefore, application of the *Vant Erve* test here is appropriate.

In *Vant Erve*, the court adopted a four-factor test to judge whether reopening the record is appropriate: "(1) the nature of the proferred new evidence; (2) the prejudice to the parties; (3) the length of the delay; and (4) the reason for the delay." *Id.* While the special master in this case may not have applied this test verbatim, the record indicates that she took the relevant aspects of the test into consideration. As stated in *Vant Erve*, the first factor, the nature of the new evidence, is "paramount," and if the new evidence is "both relevant and affective of outcome," the other factors' importance diminishes. *Id.* As stated above, the relevance of the new evidence in *Plavin* was substantial. If Dr. Gomez had in fact changed his mind or disagreed with the way his prior evidence had been analyzed, the outcome of at least some of the TS cases would likely change. In addition, while evidence that the extent of the cortical tubers influenced greatly the severity of a child's seizures or mental retardation had been present when the initial entitlement decision was made, respondent in submitting the new article stated that the article provided updated and probative evidence that this was so. In light of the potential effect of these two pieces of evidence, the special master did not abuse her discretion in reopening the proceedings.

Second, while petitioners asserted the delay and expense of continuing with the TS entitlement proceedings to show prejudice in reopening the proceedings, as the court stated in *Vant Erve*, such considerations are not of primary importance. *Id.* at 613-14. Rather, the record of Rachel's condition had been adequately preserved, and the same witnesses in the prior proceeding were coming forward with their new thoughts on TS.

See id. at 614. Therefore, petitioners were not unduly prejudiced. Third, the length of the delay was "of diminished importance" as the final judgment had not yet been entered, and the new evidence was highly probative of whether the initial grant of compensation was proper. *See id.* at 614-15. Finally, the reason for the delay, as described above, more than adequately overrode any prejudice to the parties. The special master's decision to reopen the entitlement proceedings in the TS cases was entirely proper in light of the new evidence proferred by respondent. For these reasons, the court firmly denies this portion of petitioners' motion for review.

IV. The Special Master Did Not Commit Reversible Error in Permitting Respondent to Contact Dr. Gomez, to Contract With Him, and to Present Him as a Witness

In their motion for review, petitioners further argue that "by permitting the government over objection to illegally contact the petitioners' expert Dr. Gomez, hire him away from petitioners, hide him from discovery, and ultimately to co-opt his testimony, the special master abused her discretion and acted in a manner contrary to law." Pet'rs Mem. of Objections at 64. Petitioners allege that:

> The special master **grossly** abused her discretion by allowing the government to steal away and co-opt Dr. Gomez, re-open the cases based on his equivocal and cryptic statements, and shield him from participation in trial proceedings (where he would have supported petitioners' theory of recovery), only then to allow him to present his opinion testimony, which he was induced to change **subsequent to the trial,** to favor the government's case on a peripheral and legally irrelevant point.

Id. at 67-68 (emphasis in original). Therefore, they allege that Dr. Gomez was originally their "expert" witness, and that the special master later allowed the "theft" of Dr. Gomez by respondent,

resulting in "a miscarriage and mockery of justice."[11] *Id.* at 68. Accordingly, petitioners request a remedy of sanctions, "in the form of damages for delay caused by improper conduct contrary to the interests of justice." *Id.*

The record reveals that petitioners' irresponsible and intemperate attacks upon the special master are wholly without merit. The Special Master's decision on allowing respondent to contact Dr. Gomez, and ultimately present him as a witness, was proper and not an abuse of discretion. The Vaccine Act contemplates evidentiary flexibility and informality in proceedings. The Vaccine Rules state that "[t]he special master shall determine the nature of the proceedings, with the goal of making the proceedings flexible, and less adversarial, while at the same time affording each party a full and fair opportunity to present its case . . ." Vaccine Rule 3(b). Indeed, the Vaccine Act itself mandates a "less-adversarial, expeditious, and informal proceeding" which "include[s] flexible and informal standards of admissibility." 42 U.S.C. §§ 300aa-12(d)(2). As both parties stated in their briefs, the special master is entitled to direct discovery as she sees fit and that "there shall be no discovery as a matter of right." Vaccine Rule 7. In addition, "[i]n receiving evidence, the special master will not be bound by common law or statutory rules of evidence. The special master will consider all relevant, reliable evidence, governed by principles of fundamental fairness to both parties." Vaccine Rule 8(b). In addition, "[i]n conducting a proceeding on a petition a special master . . . may require the testimony of any person . . . as may be reasonable and necessary." 42 U.S.C. 300aa-12(d)(3)(B)(iii). The special master

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[11]The record indicates that Dr. Gomez's "status" at the Mayo Clinic precluded him from contracting with any litigant, including petitioners, prior to his attaining Emeritus Status. His testimony in October, 1991 was presented through petitioners as a result of his being the attending physician for some of the TS children (other than Rachel Plavin) in the Vaccine Program. Subsequent to his attaining Emeritus status, respondent did formally contract with Dr. Gomez to be a retained expert witness in the Omnibus proceedings.

is allowed to, and frequently did in the Omnibus proceedings, ask her own questions of a witness. *See* Vaccine Rule 8(e).

Overriding the analysis of whether it was improper for the special master to allow respondent to contract with Dr. Gomez as an expert witness after petitioners had allegedly presented him as a witness at the October, 1991 hearing, is the fact that it is undisputed that Dr. Gomez is *the world's expert on Tuberous Sclerosis*. Throughout the record, he is consistently referred to as the world's expert by petitioners, respondent and the special master. For the special master to be interested in his testimony is indeed valid. The special master indicated on more than one occasion that she was not so concerned about who brought Dr. Gomez to her, she was more concerned with simply hearing his opinion on whether he had changed his mind. In fact, at one point she advised the parties on the subject of Dr. Gomez that "where someone is unique, because the area is limited in the number of people who could truly be considered experts, his testimony does not belong to anybody." *Barnes*, 92-0032V, Omnibus TS Proceedings, Tr. of Status Conf., May 30, 1997, at 15. In addition, the special master stated that "where someone has the expertise of Dr. Gomez, the fact that one side or another calls him, I frankly do not believe influences him that much." *Id.* In another status conference, the special master responded to petitioners' concerns on Dr. Gomez that:

> I've asked for Dr. Gomez forever to be here, the Government is providing him in this hearing because I asked for him. I want him because he's the world's expert, everybody defers to him in the issue of tuberous sclerosis. If he has changed his opinion about things he has said before, I want to know the basis of that. You might jump up and down and say, that's wonderful, he's not believable because he's reversed himself. Well, maybe that's true. I have to decide that.

Barnes, 92-0032V, Omnibus TS Proceedings, Tr. of Status Conf., April 11, 1997, at 22-23. Finally, in response again to the

petitioners concerns that Dr. Gomez was no longer petitioners' witness, the special master stated, "Mr. Moxley, consider [Dr. Gomez] my witness, except for the fact that I'm not paying him. I want to know certain answers to questions that I have, and he's the only one that could answer them, because he is the world's premier expert in tuberous sclerosis." *Id.* at 37.

By approving of the government's contracting with Dr. Gomez and stating that no ethical violations had occurred, the special master was focusing on her role of determining whether DPT actually had any role in "triggering" seizures in TS children. The special master was not concerned with who brought Dr. Gomez to her, she was simply concerned that he testify. In addition, the record indicates that she took into account petitioners' concerns of impropriety, and was determined to make her own credibility determination of Dr. Gomez. She ultimately gave the testimony of Dr. Gomez great weight in her findings in the TS Omnibus Decision, only after hearing petitioners' cross-examination of Dr. Gomez and by questioning Dr. Gomez herself. The court has reviewed the extensive record documenting petitioners' objections to respondent's contracting with and presenting Dr. Gomez in the Omnibus proceedings. The special master was well within the bounds of reason and in no way abused her discretion in allowing respondent to present Dr. Gomez as their witness and in discounting petitioners concerns. The record indicates and the court finds that petitioners argument is specious. Accordingly, petitioners motion for review on this issue is denied. The court also wholly denies petitioners request for sanctions.

CONCLUSION

The court has carefully investigated all of petitioners arguments and allegations, of which there are many, in petitioners motion for review. Among other things, the court has carefully reviewed all of the legal and factual conclusions of the special master in *Plavin*, which in her decision on entitlement adopted the reasoning and findings of the TS Omnibus Decision. In addition, the court has carefully reviewed the record with respect

to petitioners' arguments on the propriety of the special master's reopening the *Plavin* entitlement proceedings and with respect to Dr. Gomez as respondent's witness in the Omnibus proceedings. For the foregoing reasons, the court directs the following:

(1) petitioners' motion for review is granted with respect to the special master's finding that DPT does not generally cause infantile spasms or afebrile seizures such as the one Rachel Plavin suffered, and accordingly the court reverses the special master on this finding;

(2) the special master's finding that TS is the "factor unrelated" which causes afebrile seizures absent other symptoms of a vaccine injury is remanded for further findings with respect to;

(a) whether the special master would uphold this finding without the benefit of her finding reversed above that DPT does not generally cause infantile spasms or afebrile seizures of the type that Rachel Plavin experienced; and

(b) whether Rachel Plavin actually experienced any symptoms of an on-Table vaccine injury outside of her seizure;

(3) petitioners' motion for review is denied as to its contentions that the special master was arbitrary, capricious, or that she did not act in accordance with law in reopening the proceedings on entitlement; and

(4) petitioners' motion for review, including its request for sanctions, is denied as to its allegations that the special master allowed certain improprieties on the part of the government with respect to Dr. Gomez.

In accordance with 42 U.S.C. §§ 300aa-12(e)(2), the court orders that the special master issue her decision on remand within 90 days of this order.

IT IS SO ORDERED.

MOODY R. TIDWELL
Judge

APPENDIX G: OPINION AND ORDER OF THE UNITED STATES COURT OF FEDERAL CLAIMS, DATED MARCH 23, 1998

40 Fed. Cl. 625
United States Court of Federal Claims
March 23, 1998
No. 90-1334 V

JOHN HANLON and RUTH ANNE HANLON, Parents and Next Friends of MICHAEL HANLON,

Petitioners,

v.

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Respondent.

Robert T. Moxley, Cheyenne, WY, for petitioners.
Mary Hampton Mason, with whom were Assistant Attorney General Frank W. Hunger, Helene M. Goldberg, John Lodge Euler and Gerard W. Fischer, Washington, DC, for respondent.

OPINION and ORDER

TURNER, Judge.

Petitioners seek relief under the National Vaccine Injury Compensation Program (established pursuant to 42 U.S.C. §§ 300aa-10) for injuries suffered by their son, Michael Hanlon. Applications for and determinations of eligibility for Program compensation are controlled by 42 U.S.C. §§ 300aa-11 to -16 and -33(2)&(4) (Vaccine Act). (For convenience, we sometimes hereafter shorten references to sections of the Vaccine Act to the

portion following the hyphen.)

Petitioners allege that Michael suffered compensable injuries as a result of diphtheria-pertussis-tetanus (DPT) vaccinations. On September 15, 1997, Special Master Laura Millman issued a decision denying relief. The case stands on petitioners' motion filed October 20, 1997 to review that adverse decision. We conclude that the special master did not abuse her discretion, that she was not arbitrary or capricious, and that she acted in accordance with applicable law. Thus, we further conclude that the master's decision should be affirmed.

I

Michael was born on March 30, 1978 and received his first DPT vaccination on June 1, 1978. Decision (5/31/94) at 2. The next day, Michael suffered his first seizure. *Id.* at 3, App. at 142. Michael received three more DPT vaccinations on July 28 and October 3, 1978 and on October 1, 1979. *Id.* at 3-4. After the initial seizure, Michael suffered other seizures continuing at least through 1990. *Id.* Michael's seizures were afebrile "complex partial (focal) seizures." Decision (9/15/97) at 45. Michael was eventually diagnosed with a seizure disorder. Decision (5/31/94) at 3-4. Michael was also diagnosed as having tuberous sclerosis (TS), a genetic disease of the brain known to cause seizures and mental retardation.

On September 25, 1990, petitioners filed a petition for compensation under the Vaccine Act. On May 31, 1994, Special Master Millman filed a decision in favor of compensation. The special master found that Michael's injuries conformed in type and timing to the injuries described in the Vaccine Injury Table (Table), §§ 14. Decision (5/31/94), App. at 141-42. The special master next concluded that petitioners proved Table significant aggravation of Michael's TS condition. *Id.*, App. at 142. Finally, she concluded that two then-recent cases, *Suel v. Secretary of the Dep't of Health and Human Servs.*, 31 Fed.Cl. 1 (Fed.Cl. 1993), and *Costa v. Secretary of Dep't of Health and Human Servs.*, 26 Cl.Ct. 866 (Cl.Ct. 1992), mandated that she find in favor of

petitioners on the issue of entitlement to compensation. *Id.*, App. at 142. The special master then initiated the damages phase of the case. Prior to a ruling on damages, and thus before any final decision by the special master, respondent sought reconsideration of the liability determination.

Thereafter, the special master received more evidence on the issue of liability and ultimately held omnibus hearings in October 1996 and June 1997 "to facilitate the disposition of over twenty [TS] cases (even those in which entitlement had already been decided but which were awaiting disposition of damages)." Decision (9/15/97) at 5. The special master determined that petitioners had demonstrated a prima facie Table significant aggravation under the Vaccine Act. *Id.* at 64. The special master concluded that petitioners were entitled to a "presumption" that the vaccine significantly aggravated Michael's TS. *Id.* However, the special master also concluded that respondent had met its rebuttal burden by proving that a factor unrelated to the vaccine, TS, caused Michael's seizures as well as his "current condition." *Id.* For this reason, the special master denied compensation, *id.* at 67, and vacated her prior decision, Order (9/18/97).

On October 20, 1997, petitioners filed their motion for review of the special master's final decision.

II

The petition in a vaccine case must allege the occurrence of one or more of the following events: (1) the vaccine caused an injury listed in the Vaccine Injury Table, (2) the vaccine caused an injury not listed in the Table, (3) the vaccine aggravated an injury or "pre-existing condition" listed in the Table, or (4) the vaccine aggravated an injury or pre-existing condition not listed in the Table. §§ 11(c)(1)(C). Thus, a threshold question is whether the injury complained of or the pre-existing condition allegedly aggravated is listed in the Table.

In this case, petitioner alleges that DPT vaccine caused

Michael to suffer residual seizure disorder (RSD).([1]) The injury complained of, RSD, is listed in the Table. §§ 14(a). For this reason petitioners may proceed with the theory that the vaccine caused Michael to suffer a Table injury, keeping in mind that they must show that the *first* seizure Michael suffered, "the first symptom or manifestation of the onset" of an illness listed in the Table, "occurred within the time period after vaccine administration set forth in the Vaccine Injury Table," in this case, within three days.([2]) §§ 11(c)(1)(C)(i), 14(a).

In the alternative, petitioners allege that, "within the time frame set forth in the Vaccine Injury Table," the DPT vaccinations "significantly aggravated [Michael's] existing Tuberous Sclerosis condition." Pet. ¶ 12. The pre-existing condition allegedly aggravated, TS, is *not* listed in the Table and cannot be considered a condition listed in the Table.([3])

Because TS is not listed in the Table and cannot be considered a condition listed in the Table, petitioners must prove causation in fact with respect to the significant aggravation

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[1]Petitioners allege that "the onset of a residual afebrile seizure disorder ... is to be presumed caused by his DPT vaccinations under the provisions of the Vaccine Injury Table." Pet. ¶ 21.

[2]In accordance with the Table, petitioners must also show that the vaccinee suffered "2 or more seizures ... within 1 year after the administration of the vaccine which were unaccompanied by fever or accompanied by fever of less than 102 degrees." §§ 14(b)(2).

[3]The illnesses, disabilities, injuries and conditions "covered" for the DPT vaccine include, inter alia, encephalopathy and residual seizure disorder. §§ 14(a). We are mindful that TS has been treated as an encephalopathy or a latent seizure disorder in other cases. See, e.g., Suel v. Secretary of the Dep't of Health and Human Servs., 31 Fed.Cl. 1, 7-8 (Fed.Cl. 1993) (treating TS as a condition listed in the Table); Costa v. Secretary of the Dep't of Health and Human Servs., 26 Cl.Ct. 866, 869-871 (Cl.Ct. 1992) (holding that TS is an encephalopathy or a latent seizure disorder).

However, respondent's expert (Gomez), "the world's expert in TS," has given uncontroverted testimony that "TS is not an encephalopathy." Decision (9/15/97) at 5-6. Moreover, there is no evidence that TS is a residual seizure disorder.

portion of the case. Despite this, the special master evaluated the case as a significant aggravation case under the Vaccine Injury Table. Decision (9/15/97) at 64. Indeed, the special master found that petitioners made out a significant aggravation case under the Table. Id.

Based on our discussion of the law above, we conclude that the special master erred in so ruling. However, because petitioners were entitled to proceed under the Table by alleging that DPT caused Michael's RSD, this error is harmless. By finding that petitioners had proved Table significant aggravation, in effect, the special master found that petitioners proved Table onset: (1) Michael suffers from a condition listed in the Table, RSD, (2) the first seizure Michael suffered occurred within three days and (3) Michael suffered "2 or more seizures ... within 1 year after the administration of the vaccine which were unaccompanied by fever or accompanied by fever of less than 102 degrees." See Decision (9/15/97) at 64; Decision (5/31/94) at 5.

Because petitioners meet the requirements for proof of a Table injury (RSD), they are entitled to a presumption that the vaccine injured Michael. The presumption shifts the burden to respondent to show by a "preponderance of the evidence" that the injury was actually caused by "factors unrelated" to the vaccine. §§ 13(a)(1)(B). In this case, the special master decided that respondent had proved that a factor unrelated to the vaccine, TS, caused the initial seizure, the residual seizure disorder and any seizure-related problems from which Michael currently suffers. Decision (9/15/97) at 64. Petitioners seek review of the special master's decision. Specific objections follow.

A

Petitioners argue that the special master abused her discretion when she reconsidered, prior to her final decision, her initial finding that Michael suffered a compensable injury. Pet. Memo. of Obj. at 55. Whether or not to reconsider, prior to issuance of a final decision, an announced finding of entitlement in a vaccine case is left to the discretion of the special master.

Vant Erve v. Secretary of Health and Human Servs., 39 Fed.Cl. 607, 611-12 (Fed.Cl. 1997); McGowan v. Secretary of the Dep't of Health and Human Servs., 31 Fed.Cl. 734, 737 (Fed.Cl. 1994). Therefore, we review under the abuse of discretion standard. §§ 12(e)(2)(B); Saunders v. Secretary of Dep't of Health and Human Servs., 25 F.3d 1031, 1033 (Fed.Cir. 1994).

Petitioners claim that in order for a party to prevail on a motion to reconsider a settled entitlement issue the party must show that there is newly discovered evidence, that the evidence could not have been submitted for timely consideration, and "that the evidence would probably change the outcome of the previously adjudicated case." Pet. Memo. of Obj. at 56. We disagree. To determine whether or not the special master's decision to reopen the finding of entitlement was an abuse of discretion we simply look at the facts and circumstances surrounding her decision. But cf. Vant Erve, 39 Fed.Cl. at 612 (setting out a four-prong test for reconsideration of an entitlement decision in a vaccine case).

The special master reconsidered her finding because respondent alleged that there was new and relevant medical evidence which proved that in severe TS cases seizures are inevitable. Decision (9/15/97) at 4. This evidence would have been significant because, if respondent could prove that Michael had a severe case of TS, the evidence would suggest that TS, and not DPT, caused his seizures. For this reason, we conclude that the special master's decision to reconsider entitlement was not an abuse of discretion.

B

Petitioners also argue that the government should have been precluded from presenting a defense in its case which contradicts a defense presented in prior TS vaccine cases:

The government has on many occasions in Tuberous Sclerosis litigation sponsored witnesses who agreed that DPT 'unmasked' seizures in TS. In order to put on its omnibus defense herein, the government had to get witnesses who would sponsor

a contrary position. This is a violation of the principle of estoppel by oath ....

Pet. Memo. of Obj. at 57. Petitioners' position is without merit.

While it may be true that the government has called witnesses who have testified that DPT "unmasks" TS, it does not follow that the government is not allowed to call other witnesses or the same witnesses who, based on new or different medical research or on further reflection upon the same evidence, believe and testify to the contrary. Petitioners argument has no basis in law.

In a similar vein, petitioners argue that the government should have been collaterally estopped from presenting its defense. Pet. Memo. of Obj. at 57-58. In order for respondent to be collaterally estopped on any issue, petitioners must first show that the issue is identical to an issue litigated in a prior action. See, e.g., *Arkla, Inc. v. United States*, 37 F.3d 621, 623-24 (Fed.Cir. 1994).

Petitioners' rationale for estoppel is unclear. However, they seem to be arguing that the determination that DPT significantly aggravates TS has been decided and cannot be relitigated. The conclusion that DPT significantly aggravates TS depends upon the constantly evolving state of medical research and its application to the facts of each particular case. Under these circumstances, there is no identity of issues. We conclude that respondent cannot be estopped from presenting its "unrelated factor" defense in this case.

C

Throughout their brief, petitioners argue that the special master committed reversible error by failing to follow the "precedent" announced by judges and special masters of this court in other cases, such as *Bernard v. Secretary of Health and Human Servs.*, No. 90-2720 V, slip op. (Fed.Cl. Jan. 30, 1997), *Costa v. Secretary*, 1992 WL 365421 (Fed.Cl. Office of Special Masters) and *Suel v. Secretary of the Dep't of Health and Human Servs.*, 31

Fed.Cl. 1 (Fed.Cl. 1993). Pet. Memo. of Obj. at 46, 58-60.

In making their argument petitioners assume that the special master is bound by her prior opinions and by the opinions of the Court of Federal Claims in other cases. This assumption is mistaken. Special masters are neither bound by their own decisions nor by cases from the Court of Federal Claims, except, of course, in the same case on remand. Moreover, Bernard is an unpublished opinion and, as such, "shall not be employed as authority by [the Court of Federal Claims] and may not be cited by counsel as authority." RCFC 52.1(a).

D

Petitioners argue that TS is not a "factor[] unrelated to the administration of the vaccine" for purposes of the Vaccine Act. See §§ 13(a)(1)(B). In order for respondent to rebut petitioners' prima facie case, it must prove that a "factor[] unrelated to the administration of the vaccine" caused the purported significant aggravation. See id. Petitioners set forth three reasons why the special master erred in treating TS as a "factor unrelated."

First, petitioners argue that TS is a "cutting-edge medical uncertaint[y]" and therefore cannot meet the requirements of §§ 13(a)(2)(A) of the Vaccine Act which provides that a "factor[] unrelated to the administration of the vaccine" cannot be "idiopathic, unexplained, unknown, hypothetical, or undocumentable" Pet. Memo. of Obj. at 47. Petitioner also cites *Koston v. Secretary, Dep't of Health and Human Servs.*, 974 F.2d 157 (Fed.Cir. 1992) for the proposition that an idiopathic condition (condition of unknown cause or origin) does not meet the requirements of §§ 13(a)(2)(A).([4]) Pet. Memo. of Obj. at 51.

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[4]In Koston, the Federal Circuit held that Rett Syndrome was not a factor unrelated to the administration of the vaccine because experts did not know what caused the condition. Id. at 160-61. The Federal Circuit rejected respondent's argument that because Rett Syndrome "is present from birth ... [it] must be a factor unrelated to the vaccine." Id. at 160. See also Whitecotton v. Secretary of Dep't of Health and Human Servs., 17 F.3d 374 (Fed.Cir. 1994) (holding that micro-encephalopathy was idiopathic), rev'd sub nom. on other grounds, Shalala v. Whitecotton, 514 U.S. 268 (1995).

Whether or not TS is idiopathic is a question of fact and we review questions of fact under the arbitrary and capricious standard. §§ 12(e)(2)(B). There is ample evidence that TS is not idiopathic. An expert for respondent, Dr. Gomez, testified that TS is a "genetic disorder which is either inherited or results from a mutation." Decision (9/15/97) at 6. An expert for petitioners, Dr. Osborne, also testified that TS is genetic and identified the gene sites for the condition. Id. at 36. Dr. Osborne specifically stated that TS is not idiopathic. Id. The special master concluded that Drs. Gomez and Osborne were credible. Id. at 61. We therefore conclude that petitioners' argument that TS is idiopathic has no merit.

Second, petitioners argue that TS cannot be a factor unrelated because, to be a factor unrelated, TS must be, but is not, an "infection, toxin[], trauma ... or metabolic disturbance" with "no known relation to the vaccine involved." Pet. Memo. of Obj. at 46. See §§ 13(a)(2)(B). Petitioners assume that a factor unrelated must be an "infection, toxin[], trauma ... or metabolic disturbance[]" -- that a "'Table Case' only allows the **listed** factors to be raised."([5]) Pet. Memo. of Obj. at 46. The Vaccine Act provides:

> [T]he term "factors unrelated to the administration of the vaccine" ... may ... include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the ... [vaccinee's] illness, disability, injury, condition, or death.

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[5]Petitioners also suggest that Knudsen v. Secretary of the Dep't of Health and Human Servs., 35 F.3d 543 (Fed.Cir. 1994), addresses this issue. Pet. Memo. of Obj. at 46, 53. It does not. Knudsen interprets §§ 13(a)(2)(A), not §§ 13(a)(2)(B).

§§ 13(a)(2)(B) (emphasis added). Upon reading the statute, we conclude that the §§ 13(a)(2)(B) list is not all-inclusive. Factors unrelated may include certain conditions listed, but also may include some other condition which is not listed, so long as that other condition has "no known relation to the vaccine involved, but which in the particular case [is] shown to have been the agent ... principally responsible for causing" the vaccinee's injury. For this reason, we conclude that respondent may introduce evidence that TS is a factor unrelated.

Third, petitioners argue that "seizures, the injury in TS, cannot possibly be demonstrated as a condition with 'no known relation' to [DPT]" as required by §§ 13(a)(2)(B) of the Vaccine Act. Pet. Memo. of Obj. at 47. Petitioners argue that "where the statute itself **codifies** the 'relationship' between DPT and seizures ... the Secretary [of Health and Human Services] cannot prevail in TS cases." Id. Petitioners misconstrue the provision in question. The Vaccine Act requires that the "factor unrelated," in this case, TS, be unrelated to the vaccine. See §§ 13(a). Petitioners seem to suggest that because DPT can cause seizures and TS can cause seizures that DPT and TS are related. This point is fallacious.

For the reasons above, we conclude that the special master properly evaluated TS as a "factor[] unrelated to the administration of the vaccine."

E

Petitioners argue that the special master held them to a causation-in-fact standard after they had proved their Table case. Pet. Memo. of Obj. at 43. Petitioners cite the portion of the special master decision stating: "where a child receives DPT and remains perfectly normal (in temperature, eating, sleeping, affect, and activity) but has a seizure in three days, TS, not DPT, is the cause in fact of that seizure." Pet. Memo. of Obj. at 41-42 (citing Decision (9/15/97) at 63-64). Petitioners continue: "[t]he 'new' rule ... is that a TS petitioner will recover for a Table injury **only** if a 'real vaccine reaction' is demonstrated. The perfect fit of a TS

residual seizure disorder is no longer good enough." Pet. Memo. of Obj. at 39.

Petitioners are confusing two different stages of their case. The special master held that petitioners had proved a prima facie Table case. Decision (9/15/97) at 64. If respondent had not rebutted, the prima facie showing would be "good enough." However, respondent offered evidence to rebut petitioners' case. After reviewing all the evidence the special master found a preponderance of evidence supporting respondent's argument that TS caused the seizures. The special master then offered a scenario under which petitioners might have prevailed. Specifically, the special master opined that respondent's case would not have been as convincing if the vaccinee had had a more severe "vaccine" reaction. See id. at 62-64. Petitioners thereby were not held to a causation-in-fact standard. Respondent simply put on a strong rebuttal which itself "required" petitioners to do more than rest on their prima facie showing if they wished to prevail. We conclude that petitioners were not required to prove that DPT caused in fact Michael's seizures in order to prove a Table injury.

III

Petitioners argue that the special master erred in finding that respondent had carried its rebuttal burden because it did not prove by a preponderance of the evidence that TS caused Michael's seizures. On review, we must determine whether the special master's findings are arbitrary and capricious. See §§ 12(e)(2)(B); Saunders, 25 F.3d at 1033.

A

In order to evaluate the special master's findings we must first decide whether any evidence she relied on was irrelevant or improperly admitted.

Petitioners assert that respondent acted unethically when it retained Manuel Gomez, a pediatric neurologist, as an expert for its omnibus defense. For this reason, petitioners argue the special master erred in allowing Gomez to testify in the case. On October 21, 1991, Dr. Gomez testified at a deposition in other

cases on the relationship among TS, DPT and seizures. Decision (5/31/94) at 4. Petitioners allege that Dr. Gomez was their retained expert witness at that time. Pet. Memo. of Obj. at 65. Petitioners state that "Dr. Gomez was 'retained' when he learned of the petitioners' litigation strategy and rendered opinions." Id. at 66. Respondent disputes that Dr. Gomez was ever petitioners' retained expert. Response (11/20/97) at 43. In any case, it is undisputed that respondent ultimately retained Dr. Gomez as its expert.

As a preliminary matter we address whether Dr. Gomez was retained by petitioners as an expert witness, a fact witness, or neither. We conclude that Gomez was not any type of witness for petitioners. Petitioners have submitted no evidence that Dr. Gomez was ever a witness in their case. The only connection between Gomez and petitioners is that Gomez testified in the 1991 deposition at the request of petitioners' counsel and that Gomez's 1991 testimony was cited by the special master in her initial and omnibus decisions in this case. However, the fact that petitioners' counsel had dealings with Gomez in other cases does not mean that Gomez was a witness in this case. Additionally, the fact that the special master cited Gomez's deposition from another case to summarize what she considered to be accepted medical conclusions does not mean that Gomez was a witness in this case.

Gomez's 1991 deposition in other cases generally favored petitioners and was cited as evidence of accepted conclusions about TS and seizures in the special master's first decision in this case. Later, Gomez informed respondent that he had changed his opinion so that his prior testimony was flawed and/or incomplete. Respondent called this to the attention of the special master and doing so was entirely proper. Subsequently, respondent retained Gomez as its expert. Because the special master had relied on Gomez's first opinion, it was important to the ultimate resolution of the case to know how and why his opinion had changed.

Additionally, we firmly believe that if petitioners' counsel

realized that the special master was going to rely on Gomez's past testimony, which favored petitioners, and knew that Gomez's opinion had changed materially based on newer studies or a change in the prevailing medical opinion, petitioners' counsel would have had an ethical duty to bring this to the special master's attention.

Courts are engaged in a search for truth no matter who calls the witness.

Because petitioners have made no showing that Gomez was ever their witness, we conclude that respondent properly contacted and retained him as an expert. For this reason and because Gomez's new testimony was pivotal, we further conclude that it was not erroneous for the special master to allow Gomez to testify.

B

Petitioners argue that the special master improperly relied on evidence that tends to undermine the Vaccine Injury Table. Pet. Memo. of Obj. at 43-45. One example is the special master's reliance on expert testimony that febrile, generalized seizures are more closely associated with DPT, while afebrile, focal seizures are more closely associated with TS. Decision (9/15/97) at 45, 61-62. This type of evidence contradicts apparent Table assumptions because the Table specifically includes focal seizures as a valid vaccine-related seizure and, in the case of RSD, the Table requires afebrile seizures. See §§ 14(a), (b)(2), (b)(4). Another example is expert testimony that in TS cases a seizure with additional vaccine-related symptoms is more suggestive of a vaccine reaction than a seizure alone. Id. at 61-62. This type of evidence, petitioners say, contradicts the Table because the Table does not require that the seizure be accompanied other symptoms.([6]) See §§ 14(a).

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[6]Petitioners also argue that the portion of the special master's decision where she opines that DT does not cause seizures illustrates her attempt to "repeal" the Vaccine Injury Table. Pet. Memo. of Obj. at 44. Because petitioners do not allege that Michael suffered any injury from DT, we will not address this argument.

In evaluating petitioners' objection, it makes a difference whether the conflicting testimony is used to undermine directly a Table presumption or to prove causation in fact due to an unrelated factor. Proof of causation in fact is entirely independent of the Table. Once a Table injury or aggravation is demonstrated, plaintiff has established a prima facie case and the burden of going forward with the evidence shifts to the respondent who may, using any available evidence, attempt to prove alternative causation. Actual causation evidence would then be offered as if respondent were the party with the burden of persuasion in a separate tort case. Similarly, if petitioners had elected to assert and had attempted to prove causation in fact of an injury or an aggravation of a pre-existing condition, respondent would then have to present other evidence, independent of the Table, to rebut petitioners' showing.

Thus, we are not troubled by the special master's consideration of this evidence, nor are we surprised that modern medical research may conflict with the Vaccine Injury Table. However, it is important to note that this evidence alone would be insufficient to prove that a factor unrelated to the vaccine caused the injury. See Quinn v. Secretary of Health and Human Servs., 1992 WL 183197, at *3-4, 6-7 (Cl.Ct. Office of Special Masters) (holding proof that measles vaccine does not cause stroke is not sufficient to prove that a factor unrelated caused vaccinee's stroke).

We conclude that it was not improper for the special master to rely on causation-in-fact evidence which may have contradicted the Table.

C

Petitioners assert that the special master's finding is error to the extent that she relies on a "unity theory," rejected by Knudsen v. Secretary of the Dep't of Health and Human Servs., 35 F.3d 543 (Fed.Cir. 1994). Pet. Memo. of Obj. at 48. In Knudsen, the vaccinee had some symptoms which were consistent with the vaccine and a virus and some symptoms that

were consistent with only the virus. There, respondent's medical expert theorized that "the only single thing that could explain all of [the vaccinee's] symptoms ... was a systemic viral infection." Id. This is the "unity theory." The Federal Circuit rejected this logic because it was possible that the vaccinee had both a reaction to the DPT and a viral infection. However, Knudsen is not on point. In this case, there are no extraneous symptoms. The symptoms at issue are seizures and they are presumed to conform to a vaccine reaction unless respondent proves otherwise. The logic in this case is that the type of seizure Michael suffered is consistent with TS and inconsistent with a DPT reaction. We cannot say that such logic is arbitrary or capricious.

D

We now consider whether the special master's decision that "TS caused in fact [Michael's] initial seizure as well as [his] current condition," Decision (9/15/97) at 64, was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." §§ 12(e)(2)(B).

The special master made the following relevant findings. She found, based on the testimony of two experts, Gomez and Osborne, that "TS is the overwhelming cause of seizures in a child afflicted with the disease, unless he develops a fever or some other well-recognized reaction to a vaccination." Id. at 61-62. She found that studies "strongly indicate that there is a programmed aspect [i.e., natural, genetic timetable in children with TS] to seizure onset." Id. at 62. She found "that the presence of tubers ... the hallmark of TS, leads to seizures in the majority of TS patients." Id. at 64. And she found that "DPT does not initiate seizures in TS patients." Id. at 65.

The preceding paragraph includes all the findings relevant to TS vaccinees who, like Michael Hanlon, do not suffer from infantile spasms.([7]) Based on these findings, the special master

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[7] The special master made numerous other findings pertaining to TS children who suffer from infantile spasms. Decision (9/15/97) at 58-60.

came to a general conclusion:

> When faced with the choice of whether TS caused in fact an individual's seizure disorder so as to rebut the presumption that DPT vaccination is the cause, the court must choose the former over the latter in every case in which the vaccinee has no symptom other than the seizure.

Id. at 62. Then the special master applied her general conclusion to Michael Hanlon's case:

> [W]here a TS child receives DPT vaccine and remains perfectly normal (in temperature, eating, sleeping, affect, and activity) but has a seizure within three days, TS, not DPT, is the cause in fact of that seizure. This is so whether or not the initial seizure takes the form of an infantile spasm or some other type of afebrile seizure such as Michael Hanlon ... had.

Id. at 63-64. She later made a few additional findings for Michael Hanlon's case and reiterated her decision:

> Michael Hanlon had repetitive eye blinking occasionally between the ages of two and four months. Between the ages of four and six months, he had recurrent blinking of the eyes associated with some jerking of the head to the right. These episodes were unaccompanied by fever. He received DPT vaccinations when he was two, four, and six months of age. Petitioners alleged that onset occurred one day after the first DPT. In light of this court's above holdings, the onset of Michael's seizures was coincidental to his first DPT vaccination. By looking at the course of his seizures, one can see that they were happening without any reaction to an antigenic insult.

Id. at 65-66.

There is other evidence in the record which supports the

special master's decision. Perhaps the most significant example of such evidence is case-specific testimony by two pediatric neurologists, Drs. Gomez and Lee, that Michael's TS, not DPT, caused his seizures. Id. at 42, 55. Other evidence includes Gomez's testimony that TS causes seizures, seizures are the most common manifestation of TS and children with TS most often suffer seizures during the first year of life. Id. at 6-7. There is also evidence that (1) Michael had ten detectable tubers and there is a significant correlation between a high number of tubers, such as ten, and seizures and (2) DPT does not cause focal or afebrile seizures, the type of seizures Michael suffered. *Id.* at 7, 12, 17, 25, 45, 54.

Petitioners assert that the findings are not sufficient, in part, because of the Federal Circuit's holding in *Knudsen v. Secretary of the Dep't of Health and Human Servs.*, 35 F.3d 543 (Fed.Cir. 1994). Pet.'s Memo of Obj. at 48-50. In Knudsen, a special master found that petitioners had made out a prima facie case and were entitled to a presumption that DPT caused Debra Ann Knudsen to suffer an encephalopathy. Id. at 546. However, the special master also found that "at the time Debra suffered the encephalopathy, she was also suffering from a systemic viral infection, and that the viral infection in fact caused the encephalopathy and the DTP vaccine did not." Id. In Knudsen, the special master had based the decision, in part, on a finding that "encephalopathies caused by DTP vaccine occur less frequently than encephalopathies caused by viral infection." *Id.* The Court of Federal Claims upheld the findings. *Id.* The Federal Circuit reversed. The Circuit stated, "[a]lternative causation is not automatically proved simply by the mere fact that a child is infected with a virus ... at the time of vaccination or injury." *Id.* 549. The court continued:

> "[E]vidence that there are more occurrences of encephalopathies caused by viral infections than there are encephalopathies caused by DTP vaccines ... is not evidence that in a particular case

> an encephalopathy following a DPT vaccination was in fact caused by a viral infection present in the child and not caused by the DPT vaccine. "

Id. at 550.

We find Knudsen distinguishable from the master's decision in the instant case. The rationale of the portion of Knudsen we now address was that the "mere" fact that a child had a viral condition which could explain alternative causation, or the "bare statistical fact" that there are more reported cases supporting a non-vaccine cause for a Table condition than reported cases supporting a vaccine cause, does not, standing alone, prove alternative causation. *Id.* at 549, 550.

In contrast, the special master's decision under review found that in a TS child exhibiting the kind of seizures that Michael had and having the absence of all other symptoms typical in a child suffering DPT-induced seizures. "TS is the overwhelming cause of seizures" and that "DPT does not initiate seizures in TS patients." Decision (9/15/95) at 61-62, 65. In support of these conclusions, the master recited, inter alia, evidence that DPT simply does not cause the kind of seizures that Michael suffered and that two pediatric neurologists, including one the master regarded as the world's leading expert on TS, opined that TS, not DPT, caused Michael's seizures. Id. at 42, 54-55. We find this combination of conclusions and evidentiary support different from "the bare statistical fact" focused upon in Knudsen.

We conclude that the special master's decision, that respondent had proved by a preponderance of the evidence that a factor unrelated to Michael Hanlon's DPT vaccinations was the actual cause of his residual seizure disorder, is neither arbitrary, capricious, an abuse of discretion or contrary to law.

IV

Based on the foregoing, the special master's decision filed September 15, 1997 is AFFIRMED. Accordingly, it is ORDERED that judgment shall be entered in favor of respondent.

Each party shall bear its own costs.

James T. Turner
Judge

APPENDIX H: DECISION OF THE OFFICE OF SPECIAL MASTERS IN AND FOR THE UNITED STATES COURT OF FEDERAL CLAIMS, DATED JUNE 16, 1998

1998 WL 408793
In the United States Court of Federal Claims
OFFICE OF THE SPECIAL MASTERS
No. 91-1555V

MARC PLAVIN and TONI REISS, Parents and Next Friends of RACHEL LEAH REISS-PLAVIN,

Petitioners,

vs.

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Respondent.

Robert Moxley, Cheyenne, WY, for petitioners.
Karen P. Hewitt, Washington, DC, for respondent.

REPORT ON REMAND

MILLMAN, Special Master

STATEMENT

In his Order filed March 19, 1998, the Honorable Moody R. Tidwell remanded to this court the following issues for the undersigned's determination:

> (a) whether the undersigned would uphold my prior finding that tuberous sclerosis (TS) is the factor unrelated which causes afebrile seizures, absent other symptoms of a vaccine injury, without considering that DPT does not generally cause infantile spasms or afebrile seizures, and (b) whether Rachel Plavin actually experienced any symptoms of an on-Table vaccine injury

outside of her seizure.

Plavin, slip op. at 22.

In order to respond to these questions, the undersigned held a hearing on May 6, 1998 in which Mrs. Toni Reiss testified.

TESTIMONY

Mrs. Reiss testified that Rachel received her second DPT vaccination on September 15, 1989.[8] Tr. at 15, 16. Mrs. Reiss was aware of the possibility of a vaccine reaction and watched Rachel for symptoms such as a high fever and a high-pitched scream. Tr. at 16.

Mrs. Reiss testified that Rachel did not like getting vaccinated. Tr. at 17. After her DPT, she was unhappy and cried a little more than usual.[9] Id. Rachel's arm tremored.[10] Tr. at 18. This occurred only when Rachel was breast-feeding. Tr. at 32. Mrs. Reiss testified that, after her DPT, Rachel responded differently when she nursed. Tr.at 18. She would release the nipple and stare blankly. Id. Mrs. Reiss described Rachel as being "fussy" after vaccination.[11] Tr. at 18-19.

Mrs. Reiss testified that she called her pediatrician, Dr. Jacqueline Campbell, and told her about the tremor and staring.[12]

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[8]Although Mrs. Reiss could not remember the exact time of Rachel's vaccination, she testified that Rachel received her DPT between 10:00 a.m. and 2:00 p.m. Tr. at 15.

[9]Mrs. Reiss did not recall how long Rachel cried. Tr. at 17.

[10]Mrs. Reiss testified that there were two to four hours between Rachel's DPT and her onset of seizures. Tr. at 15-16.

[11]When Mrs. Reiss described Rachel as "fussy," she did not mean that Rachel was severely irritable. Tr. at 21. Rather, she defined "fussy" as crying more than usual. Id.

[12]Dr. Campbell's phone log as well as a letter she wrote dated March 15, 1991 were submitted regarding the onset of Rachel's seizures. Med. recs. at 289; P. Ex. 6. In the letter, Dr. Campbell wrote that Mrs. Reiss called her on September 15, 1989 to discuss Rachel's fussiness and apparent abdominal cramping. Med. recs. at p. 289. She also mentioned that Rachel had a brief arm tremor without other symptoms. Id.

Tr. at 19. Mrs. Reiss stated that Dr. Campbell did not seem concerned about the arm tremoring, telling her that little babies jerk a lot. Id. Mrs. Reiss could not recall if Dr. Campbell asked her if Rachel had either a fever or was severely irritable. Tr. at 20, 21. However, Mrs. Reiss testified that Rachel did not have a fever or a high-pitched cry after her vaccination. Id. Rachel did have gas intermittently. Tr. at 22.

Mrs. Reiss testified that she called her friends, Allison Brown-Rice[13] and Sandy Hough,[14] to inquire about Rachel's behavior. Tr. at 27.

On September 25, 1989, Rachel had a more serious seizure. Tr. at 36. She was hospitalized on September 26, 1989. Tr. at 43, 45. Upon Rachel's admission to the hospital, Dr.

There is no mention of blank staring. The letter further reflects that a subsequent phone call was made on September 25, 1989. Id. During this call, Mrs. Reiss told Dr. Campbell that Rachel was having brief episodes of blank staring. Id. Later that evening, Mrs. Reiss called again and spoke to Dr. Taylor. Med. recs. at 289. She told him that Rachel was experiencing left arm twitching, blank staring, and eye and head deviation to the left. Id. Dr. Campbell's phone log reflects that Mrs. Reiss called Dr. Campbell on September 9, 1989, which was six days before the vaccination. P. Ex. 6. The notation for this call reflects that Rachel had abdominal pain. Id. Dr. Campbell prescribed a hot water bottle and rectal stimulation. Id. The log then records a telephone call from Mrs. Reiss on September 15, 1989. Id. However, the date in this entry actually looks as if it originally read "September 25, 1989," with the "2" being overwritten by a "1." This entry states that Rachel "was better now crampy" and notes that she had a hand tremor. P. Ex. 6. Dr. Campbell prescribed Mylicon. Id.
It is unclear to the court how Dr. Campbell assumes, as reflected by her March 1991 letter, that there were two calls on September 25, 1989 when the phone log only records one call on that date. The only entry dated September 25, 1989 states "fussy [or funny] spell, probably needs EEG," at 8:56 p.m. (i.e. 2056). P. Ex. 6.

[13]Allison Brown-Rice submitted an affidavit stating that Mrs. Reiss called her on September 17, 1989. P. Ex. 4. The affidavit reflects that Mrs. Reiss was concerned about Rachel who, for the past two days, had been staring absently. Id. Rachel had never had staring episodes prior to her vaccination. Id.

[14]Sandra L. Hough submitted an affidavit which stated that Mrs. Reiss called her on September 15, 1989. P. Ex. 5. The affidavit reflects that Mrs. Reiss was concerned that Rachel was having a vaccine reaction because she had a left arm tremor, fussiness, staring, and was less attentive since her DPT. Id.

Campbell wrote a history which reflects that Rachel had no reaction after her second DPT. Tr. at 47-48. Mrs. Reiss did not recall specifically discussing whether Rachel had a vaccine reaction with Dr. Campbell when Rachel was hospitalized.[15] Tr. at 48.

DISCUSSION

Mrs. Reiss' testimony as well as Dr. Campbell's phone log and hospital admission history clearly show that Rachel did not manifest many of the symptoms that the Vaccine Act defines as encephalopathy. Rachel did not experience a high-pitched cry, inconsolable screaming, anorexia, insomnia, or severe irritability after her vaccination. Although she had gas after the vaccination, she experienced abdominal pain before the DPT. That she was "fussy," i.e, cried more than normal, is too general a symptom to ascribe to a serious reaction.

The undersigned finds questionable whether or not Rachel's onset of symptoms occurred on-Table. An affidavit and letter written by Dr. Campbell as well as her contemporaneous phone log and deposition testimony discuss the issue of onset; however, this evidence contains numerous discrepancies.

Dr. Campbell's affidavit states that she is "certain that the first call from the Plavins dealing with tremors did occur on September 15, 1989, and that they subsequently called on September 25, 1989, reporting the same symptoms." P. Ex. 9, p. 4. In her deposition, she also stated that Mrs. Reiss called her on September 15, 1989. P. Ex. V, p. 2-3. She stated that she is certain that her phone log refers to September 15, 1989, regardless of how the entry is written, because she wrote such

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[15] In an affidavit dated May 19, 1993, Dr. Campbell explained that when she stated that Rachel did not have a DPT reaction in the hospital admission history, she was specifically referring to whether Rachel had symptoms such as a high fever, high-pitched cry, and severe irritability. P. Ex. 9, p. 3. This statement was not, however, referring to her seizures. Id.

On June 20, 1994, Dr. Campbell's deposition was taken. P. Ex. V. In her deposition, Dr. Campbell stated that she inquires about the above symptoms when determining if a patient has suffered a vaccine reaction. P. Ex. V, p. 6.

entry herself. P. Ex. V, p. 3. However, in her March 1991 letter, Dr. Campbell stated that there were two calls made by Mrs. Reiss on September 25, 1989.

It is difficult for the court to ascertain a date for onset date based on this evidence. Although Dr. Campbell adamantly states that the phone log reflects a call on September 15, 1989, the date in this entry looks like September 25, 1989. In her deposition, she stated that she reaches this conclusion based on her personal knowledge of the call; however, she further noted that she has no independent recollection of these events. P. Ex. V, pp. 2-3. If the court were to accept that a call was made on September 15, 1989, then there is only one call on September 25, 1989, Dr. Taylor's notation at 8:56 p.m. (2056), meaning that Dr. Campbell's 1991 letter is in error.

Assuming arguendo that there was on-Table onset, the undersigned does not believe that Rachel's seizures are part of an overall vaccine reaction because she did not experience the symptomatology that would encompass such a reaction. In the absence of fever, anorexia, high-pitched crying, insomnia, excessive irritability, or inconsolable screaming, the court is hard-pressed to see anything more than the working out of Rachel's TS coincidentally on the date of the DPT vaccination.

The court relies on the opinions of Dr. Mary Anne Guggenheim (R. Ex. W) and Dr. Manuel R. Gomez (R. Ex. X). Both Drs. Guggenheim and Gomez ascribe Rachel's seizure disorder and current condition to her TS.[16] Rachel has 43 cortical

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[16]Dr. Guggenheim opined:

> In my opinion, the cause for [Rachel's] seizures was tuberous sclerosis. This condition results in abnormal brain development, including cortical tubers. Cortical tubers reflect disordered development of the cerebral cortex. These areas of abnormal neurons have been shown to be the source of epileptogenic disturbance in the cerebral cortex and the direct cause of seizures in individuals with T.S. . . . Thus, everything that we know about Rachel Plavin's symptoms is entirely consistent with tuberous sclerosis being the cause of her neurologic problems. Onset of

tubers. R. Ex. W, p. 2. One of her tubers is located in the right cerebral cortex in an anatomic site consistent with her seizures and weakness in the left side of her body. Id.

Both doctors opined that TS, particularly in a severe case, manifests itself in a seizure disorder, with consequent mental retardation. R. Ex. W, p. 2; R. Ex. X, pp. 1-2. Drs. Guggenheim and Gomez stated that the onset of Rachel's seizures, the type of seizures she had, their course, and Rachel's development are all consistent with her having TS. Id. Dr. Gomez opined that Rachel's seizures originated in her cortical tubers.[17] R. Ex. X, p. 3.

In addition, Dr. Gomez noted that the medical records suggest, through the independent evaluations of Dr. William Robertson and Dr. Robert J. Baumann, that Rachel's onset of seizures began prior to her second DPT vaccination. R. Ex. X, p. 3. These evaluations are based on the histories that Mrs. Reiss gave to the doctors. Since the onset of TS seizures normally is

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> seizures during the first few months of life is common in children with severe TS. The fact that hers were first noticed on the same day that she received a. DPT immunization is entirely coincidental.

R. Ex. W, p. 2.

[17] Dr. Gomez stated:

> Rachel's epileptic seizures began as mild, short-lasting complex partial or partial motor attacks . . . [The seizures] gradually increased in frequency, severity and duration without generalization of the motor component. The seizures became refractory to all anticonvulsant medications tried. All the above mentioned symptoms and signs are expected manifestations of cortical tubers during infancy. The gradual worsening of the seizures over a period of weeks or months, generally from the second or third month of life is predictable in patients with tuberous sclerosis....

P. Ex. X, p.1.

subtle, it is not surprising that Mrs. Reiss gave contemporaneous histories which conflict with her testimony of on-Table onset. This further indicates that there was no "black and white" distinction between Rachel's condition pre- and post-DPT vaccination. This is typical of a TS insidious onset of seizures.

The court is less impressed with the supplemental report of petitioners' expert Dr. Marcel Kinsbourne (P. Ex. 80), which reads more like a legal document, heavily emphasizing his interpretation of epidemiological data,[18] rather than a medical analysis of the nature of TS and Rachel's case. Dr. Kinsbourne is "relitigating" the data described in the court's opinion in its Omnibus Decision,[19] rather than dealing with the nature of TS, the timing of the onset of Rachel's seizures, the type of seizures she had, and her ultimate outcome. Dr. Kinsbourne's report is not responsive to the undersigned's mandate to deal with two specific questions.

The court relies heavily on Dr. Gomez' opinion as he is the world's expert on TS. Having spent his professional life studying the disease as well as treating TS patients, Dr. Gomez is amply qualified to offer his opinion on the characteristics of TS patients, the expected course of their disease, and their ultimate outcome. Unlike Dr. Kinsbourne, both Dr. Gomez's and Dr. Guggenheim's opinions rely on their medical knowledge of TS and how TS bears on Rachel's case. Based on their opinions, the court holds that TS is the factor unrelated to the DPT vaccine that caused Rachel's seizure disorder and current condition.

Ignoring, as Judge Tidwell directed, whether or not DPT can cause infantile spasms or other afebrile seizures, the court holds that in Rachel's case, absent any indicia of a vaccine

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[18]The Federal Circuit warned in Knudsen v. Secretary, HHS, 35 F.3d 543, 550 (Fed. Cir. 1994), against reliance on "bare statistical fact."

[19]Barnes et al. v. Secretary, HHS, 1997 WL 620115 (Fed. Cl. Spec. Mstr. Sept. 15, 1997).

reaction, respondent has successfully proved that TS caused in fact Rachel's seizures and current condition.

CONCLUSION

(a) I uphold my prior finding that TS is the factor unrelated which causes afebrile seizures absent other symptoms of a vaccine injury without considering that DPT does not generally cause infantile spasms or afebrile seizures, and

(b) I hold that Rachel Plavin did not actually experience any symptoms of an on-Table vaccine injury outside of her seizure.

DATED: June 16, 1998

s/
Laura D. Millman
Special Master

APPENDIX I: ORDER OF THE UNITED STATES COURT OF FEDERAL CLAIMS, DATED AUGUST 25, 1998

41 Fed. Cl. 671 (1998)
No. 91-1555 V
(FILED: August 25, 1998)

MARC PLAVIN and TONI REISS, Parents and Next Friends of RACHEL LEAH REISS-PLAVIN,

Petitioners,

v.

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Respondent.

Robert T. Moxley and Richard Gage, Cheyenne, Wyoming, for petitioners.
Mary Hampton Mason and Karen P. Hewitt, Washington, D.C., for respondent, with whom were Assistant Attorney General Frank W. Hunger, Director Helene M. Goldberg, Deputy Director John Lodge Euler, and Assistant Director Gerard W. Fischer

ORDER

TIDWELL, Senior Judge:

This case is again before the court after the special master's "Report on Remand," filed June 16, 1998. *Plavin v. Sec. of HHS*, No. 91-155V (Fed. Cl. Sp. Mstr. June 16, 1998) ("Report on Remand"). As a result of a request by petitioners, this court also allowed the parties to file "post-remand comments," which were filed on July 1, 1998 by petitioners and on July 8, 1998 by respondent. Previously, on March 19, 1998, this court issued its order on petitioners' motion for review of the September 18, 1997 decision of the special master denying compensation to Rachel

Plavin ("Rachel") under the National Childhood Vaccine Injury Act ("Vaccine Act"), 42 U.S.C. §§ 300aa-1-34 (1994). *Plavin v. Sec. of HHS,* No. 91-1555V (Fed. Cl. Mar. 19, 1998) ("Remand Order"). Such order remanded the captioned case for findings on two narrow issues related to the special master's finding that tuberous sclerosis ("TS") is the "factor unrelated" that caused Rachel's condition: (1) whether the special master would uphold that finding without considering the finding that DPT does not generally cause infantile spasms or afebrile seizures of the type that Rachel experienced; and (2) whether Rachel actually experienced any symptoms of a vaccine injury outside of her seizure. *Id.* at 22. On April 21, 1998, while the case was on remand to the Special Master, this court denied petitioners' request, filed April 8, 1998, to expand the scope of the remand proceedings. *Plavin v. Sec. of HHS,* No. 91-1555V (Fed. Cl. Apr. 21, 1998). The Special Master had also previously denied petitioners' request to expand the scope of the remand proceedings. *Plavin v. Sec. of HHS,* No. 91-1555V (Fed. Cl. Sp. Mstr. Apr. 7, 1998).

On remand, the special master held a hearing on May 6, 1998 to allow petitioners the opportunity to present evidence on the remand issues. The petitioners chose to present at the hearing only the testimony of Rachel's mother, Ms. Reiss. During the telephonic hearing, Ms. Reiss testified as to her recollection of Rachel's behavior before and after Rachel's September 15, 1989 DPT vaccination. In addition, the court and the parties questioned Ms. Reiss about her recollection of the events set forth in the written records of Dr. Jacqueline Campbell, Rachel's pediatrician at the time of the vaccination. The parties also submitted the transcribed testimony of Dr. Jacqueline Campbell, previously taken on June 20, 1994, and confirmed as accurate by Dr. Campbell in a letter dated May 27, 1998. *See* Pets. Ex. 78; Resp. Exs. V and Y. The special master also allowed the parties to file remand briefs. In addition, expert reports were submitted by both parties that interpreted the evidence obtained during the remand proceedings. Petitioners filed the report of Dr. Marcel

Kinsbourne, and respondent filed the reports of Dr. Manuel Gomez and Dr. Mary Anne Guggenheim. Pets. Ex. 80; Resp. Exs. W and X. Based upon all of the evidence and briefs filed during the remand proceedings, the special master concluded that Rachel's seizures were not "part of an overall vaccine reaction because she did not experience the symptomatology that would encompass such a reaction." Report on Remand at 6. The special master further stated that "[i]n the absence of fever, anorexia, high-pitched crying, insomnia, excessive irritability, or inconsolable screaming, the court is hard-pressed to see anything more than the working out of Rachel's TS coincidentally on the date of the DPT vaccination." *Id.* Presumably in response to this court's concern over whether Dr. Campbell's notation in the record of Rachel's "fussiness" could signal a vaccine reaction, *see* Remand Order at 16, the special master found, after the questioning on this issue during the remand hearing, that being "'fussy', i.e. cr[ying] more than normal, is too general a symptom to ascribe to a serious reaction" in this case. *Id.* at 5. Finally, the special master stated that "[a]lthough [Rachel] had gas after the vaccination, she experienced abdominal pain before the DPT." *Id.*

In her report, the special master stated that she found credible and reliable the reports of Drs. Gomez and Guggenheim, which opined that the cause of Rachel's seizures and current condition was TS alone, and not her vaccination. In their reports, the doctors explained in detail the factors leading up to their conclusions on Rachel's case. The special master stated in her report that she relied most heavily on the report of Dr. Gomez, the world's expert on TS. The special master found less credible the report of Dr. Kinsbourne, which was characterized as largely unresponsive to the narrow issues on remand, and as an attempt to relitigate issues addressed in the TS Omnibus proceeding.

The special master therefore concluded that "TS is the factor unrelated to the DPT vaccine that caused Rachel's seizure disorder and current condition." *Id.* at 8. In addition, the special master held that "[i]gnoring, as Judge Tidwell directed, whether

or not DPT can cause infantile spasms or other afebrile seizures, the court holds that in Rachel's case, absent any indicia of a vaccine reaction, respondent has successfully proved that TS caused in fact Rachel's seizures and current condition." *Id.*

As explained in detail in this court's March 19, 1998 order, in reviewing decisions, findings and conclusions of the special master, the court may (1) uphold the findings of fact and conclusions of law and sustain the decision, (2) set aside any findings of fact or conclusions of law found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law," or (3) remand the petition to the special master for further action in accordance with the court's direction. 42 U.S.C. §§ 300aa-12e(2). The court reviews findings of fact and law under the narrow "arbitrary and capricious" standard. *See McCarren v. Secretary of HHS*, 1997 WL 801447 at *1-*3 (1997). The scope of review is exceedingly narrow; a court "may not substitute its own judgment for that of the special master if the special master has considered all relevant factors, and has made no clear error of judgment." *Costa v. Secretary of HHS*, 26 Cl. Ct. 866, 868 (1992) (quoting *Loe v. Secretary of HHS*, 22 Cl. Ct. 430, 432 (1991)).

The court is very satisfied with the special master's handling of the proceedings on remand. This court in its March 19, 1998 order gave very specific instructions as to the issues to be addressed during the remand proceedings. The special master allowed the parties a chance to present any fact witnesses to testify as to such issues, and to present such witnesses in person, although the parties chose to hold the hearing by telephone. In addition, the parties were permitted to file expert reports and any additional documents for the record in support of their positions. Finally, the special master allowed the parties to file briefs on remand. In the Report on Remand, the special master more than adequately addressed the court's concerns in the March 19, 1998 order and reached factual conclusions based upon rational findings of credibility and an accurate and complete understanding of the voluminous record in this case. Accordingly,

after careful consideration of the proceedings and findings on remand, this court holds that the special master's decision on remand was well in accordance with law, and was not arbitrary, capricious or an abuse of discretion.

At the request of petitioners, in a June 23, 1998 order this court permitted the parties to file limited comments on the special master's report on remand. Despite this court's order that such comments be limited "strictly to the remand proceedings and findings," petitioners filed a lengthy brief largely attempting to again raise many of the TS Omnibus issues. This court refers petitioners to the March 19, 1998 order in response to many of petitioners' arguments. Petitioners' sole argument relevant to the remand proceedings was that the special master failed to adequately put aside the finding that DPT does not generally cause afebrile seizures of the type that Rachel experienced in making the findings on remand. After reviewing petitioners' extensive remarks on this issue, and after a review of the proceedings and the basis for the special master's findings on remand, however, the court wholly disagrees with petitioners. The special master properly set aside what petitioners call the "seizure-type" theory, and instead relied on extensive fact-specific evidence indicating that Rachel's condition was due to a factor unrelated to her DPT vaccine, i.e., her pre-existing TS. Accordingly, after carefully considering all of petitioners' arguments in their memorandum in support of their motion for review, and respondent's comments in response to petitioners' brief, this court disagrees with petitioners' post-remand comments and affirms the findings of the special master.

CONCLUSION

This court has carefully considered all of petitioners' concerns voiced in its July 1, 1998 post-remand comments. As to the limited issues on remand, the court is satisfied with the findings and support for those findings by the special master. The limited and general finding that DPT does not generally cause infantile spasms or afebrile seizures such as the one Rachel suffered was reversed in this court's March 19, 1998 remand

order. The Report on Remand, however, which is affirmed by this court, found that even without that finding, the prior denial of entitlement to a program award in the captioned case should be upheld. Accordingly, petitioners' motion for review and memorandum in support of its motion for review, filed October 20, 1997, and petitioners' post-remand comments, filed July 1, 1998, are DENIED. The effect of such denial is that the special master's finding that Rachel Plavin is not entitled to a program award is affirmed. The Clerk shall enter judgment accordingly.

As a final note, petitioners' counsel are forewarned to cease their repeated attempts to discredit the Special Master, for example by sarcastically referring to her as "Dr. Millman" in their post-remand comments, as this is not looked upon kindly by this court. While petitioners certainly should have the opportunity to discredit or question the conclusions of any jurist, personal attacks are wholly unnecessary and improper. This court, therefore, will repeat its warning to petitioners in the March 19, 1998 Remand Order that "petitioners' irresponsible and intemperate attacks upon the special master are wholly without merit." Remand Order at 20.

IT IS SO ORDERED.

MOODY R. TIDWELL

Senior Judge

APPENDIX J: OPINION AND ORDER OF THE UNITED STATES COURT OF APPEALS IN AND FOR THE FEDERAL CIRCUIT, DATED SEPTEMBER 8, 1999

191 F.3d 1344 (Fed. Cir. 1999)

United States Court of Appeals for the Federal Circuit
98-5120

JOHN HANLON and RUTH ANN HANLON, Parents and next friends of Michael Hanlon,

Petitioners-Appellants,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent-Appellee.

DECIDED: September 8, 1999

Before MAYER, Chief Judge, LOURIE, Circuit Judge, and BLACK, District Judge.

MAYER, Chief Judge.

John and Ruth Ann Hanlon appeal the judgment of the United States Court of Federal Claims, Hanlon v. Secretary of Health and Human Services, 40 Fed. Cl. 625 (1998), affirming the special master's denial of their claim under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34 (1994 & West Supp. 1999) ("Vaccine Act"). Because the special master and the Court of Federal Claims properly evaluated their petition, we affirm.

Background

Michael Hanlon was born on March 30, 1978 with

tuberous sclerosis ("TS"), a genetic disorder that results in cortical lesions or tubers on the brain. On June 1, 1978, he received his first Diphtheria-Pertussis-Tetanus ("DPT") vaccination and suffered his first seizure the next day. Michael continued to suffer from episodes of focal afebrile (without fever) seizures through 1990. His parents filed a petition under the Vaccine Act on September 26, 1990, seeking compensation for the seizures allegedly caused by Michael's DPT vaccination.

In a May 31, 1994 decision, the special master determined that because the first seizure occurred within three days of Michael's first DPT vaccination, the Hanlons' claim fell under the Vaccine Injury Table ("Table"). See 42 U.S.C. § 300aa-14. Finding that the DPT vaccine had significantly aggravated Michael's TS, the special master held that compensation was appropriate under the Vaccine Act. The main evidence supporting this conclusion was testimony given in 1991 by Dr. Manuel Gomez, the world's leading expert in TS. See Costa v. Secretary of Dep't of Health and Human Servs., 1992 WL 47334, at *5-*8 (Cl. Ct. Sp. Mstr. Feb. 26, 1992). Dr. Gomez said that seizures were the most common presenting symptom in TS patients. See id. at *7. He also stated that the DPT vaccine could not aggravate TS itself; rather, it may aggravate or induce TS seizures. See id., at *8.

Prior to a ruling on damages, the Secretary of Health and Human Services ("the Secretary") successfully sought reconsideration of the liability determination in light of new evidence showing that a "factor unrelated" to the DPT vaccine caused Michael's focal afebrile seizures. Subsequently, in a September 15, 1997 omnibus decision, the special master denied compensation. See Barnes v. Secretary, Dep't of Health and Human Servs., 1997 WL 620115 (Fed. Cl. Sp. Mstr. Sept. 15, 1997). The special master held that, although the Hanlons demonstrated "significant aggravation" of a Table injury, see 42 U.S.C. § 300aa-33(4), the Secretary successfully rebutted the statutory presumption by proving that a factor unrelated to the DPT vaccine caused the seizures, see id. § 300aa-13(a)(1)(B). In

particular, the Secretary presented several recent studies indicating that TS caused the type of seizures—afebrile—that Michael suffered. Based on this new evidence, Dr. Gomez testified that, contrary to his previous opinion, the cortical lesions in Michael's brain, due to TS, were the sole cause of both his initial seizure onset and his current residual seizure disorder. See Barnes, 1997 WL 620115, at *22-*25. After weighing voluminous evidence on the relationship between seizures and both TS and the DPT vaccine, the special master concluded that "where a TS child receives DPT vaccine and remains perfectly normal (in temperature, eating, sleeping, affect, and activity) but has a seizure within three days, TS, not DPT, is the cause in fact of that seizure." Id. at *33. Thus, given the number of cortical tubers on Michael's brain (at least ten), the special master concluded that his preexisting TS was the actual cause in fact of his seizures and that their onset was merely "coincidental to his first DPT vaccination." Id. at *34.

The Hanlons sought review of the decision in the Court of Federal Claims. They argued that TS could not be a factor unrelated because it was not an "infection, toxin[], trauma, or metabolic disturbance[]" under section 300-aa14(b)(3)(B); challenged the special master's factual findings; and asserted that if the findings were correct, they were insufficient to show causation under the Vaccine Act. The Hanlons also claimed that the Secretary unethically retained Dr. Gomez while he was their expert witness.

The Court of Federal Claims held that the Vaccine Act permitted consideration of TS as a factor unrelated to the DPT vaccine. See 40 Fed. Cl. at 631. Moreover, it found no evidence to support the contention that the Secretary had "stolen" Dr. Gomez from the Hanlons. See id. at 632. The court did hold that the special master erred in characterizing the claim as a significant aggravation case since TS was not a condition listed in the Table. See id. at 628. This error was harmless, however, because Michael's seizures still satisfied the requirements for the

presumption of a Table injury—i.e., a residual seizure disorder.[1] See id. Finally, the Court of Federal Claims affirmed the special master's conclusion that the Secretary had proved by a preponderance of the evidence that Michael's TS was a factor unrelated to the DPT vaccine that actually caused his seizures. See id. at 635. The Hanlons appeal.

Discussion

The Hanlons challenge both the special master's factual findings, as affirmed by the Court of Federal Claims, and the court's interpretation of the Vaccine Act. Under the Vaccine Act, the Court of Federal Claims may not disturb the factual findings of the special master unless they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 42 U.S.C. § 300aa-12(e)(2)(B). Because it is a legal conclusion, we review de novo the court's affirmance of the special master's factual determinations. See Hines v. Secretary of Dep't of Health and Human Servs., 940 F.2d 1518, 1524 (Fed. Cir. 1991). "In effect . . . we review the underlying decision of the special master under the arbitrary and capricious standard of § 300aa-12(e)(2)(B)." Id. Statutory interpretation is a question of law, which we review de novo. See Martin v. Secretary of Dep't of Health and Human Servs., 62 F.3d 1403, 1405 (Fed. Cir. 1995).

After establishing that Michael suffered from a Table injury, the Hanlons are entitled to compensation unless the Secretary shows, by a preponderance of the evidence, that a factor unrelated to the vaccine caused the injury. See Knudsen v. Secretary of Dep't of Health and Human Servs., 35 F.3d 543, 547 (Fed. Cir. 1994); 42 U.S.C. § 300aa-13(a)(1)(B). Thus, once the special master finds "causation between the vaccine and the injury, [s]he is required under the Vaccine Act to make a further finding on the question of alternative causation." Knudsen, 35

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[1]On March 10, 1995, the United States Department of Health and Human Services removed residual seizure disorders from the Table due, in part, to the Institute of Medicine's statement that "afebrile seizures are not causally related to DPT vaccine." 60 Fed. Reg. 7678, 7690 (1995).

F.3d at 551. This inquiry "involves ascertaining whether a sequence of cause and effect is 'logical' and legally probable, not medically or scientifically certain." Id. at 548-49 (describing the standard for causation in off-Table cases, and holding that this standard is the same for alternative causation).

The Hanlons first argue that Michael's TS cannot be used to rebut his Table injury. Because section 300aa-14(b)(3)(B) refers only to "infection, toxins, trauma, or metabolic disturbances," TS cannot be a factor unrelated to the vaccine. This contention misconstrues the Vaccine Act. Section 300aa-14(b)(3)(B) applies only when determining whether there is a Table injury. Once a Table injury is established, the Secretary may rebut the presumption pursuant to section 300aa-13(a)(2), which states that "'factors unrelated to the administration of the vaccine' . . . may . . . include infection, toxins, trauma . . . , or metabolic disturbances." (emphasis added). The Court of Federal Claims, therefore, did not err in considering TS as the alternative cause of Michael's Table injury.

The Hanlons further challenge the special master's factual finding that TS was the actual cause of Michael's seizures. There is ample support in the record for this determination; it was not "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 42 U.S.C. § 300aa-12(e)(2)(B).

While the Hanlons acknowledge the role of TS in ongoing seizures, they dispute the finding that TS causes the onset of seizures. In making this determination, the special master relied on several studies that concluded that TS, not the DPT vaccine, causes afebrile seizures. Moreover, Dr. Gomez stated that the cause of Michael's seizure onset was "the cortical issues in the brain, which is part of tuberous sclerosis," and that the DPT vaccine did not have "any effect in the course of the disease." Given his reputation as the world's expert in TS and the quality of his testimony, the special master found that Dr. Gomez was the most credible witness. See Barnes, 1997 WL 620115, at *32. Such credibility determinations are "virtually unreviewable." Bradley v. Secretary of Dep't of Health and Human Servs., 991

F.2d. 1570, 1575 (Fed. Cir. 1993). Accordingly, we agree with the Court of Federal Claims that the special master was not arbitrary or capricious in finding that "where a TS child receives DPT vaccine and remains perfectly normal (in temperature, eating, sleeping, affect, and activity) but has a seizure within three days, TS, not DPT, is the cause in fact of that seizure. This is so whether or not the initial seizure takes the form of an infantile spasm or some other type of afebrile seizure such as Michael Hanlon . . . had." Barnes, 1997 WL 620115, at *33.[2]

The Hanlons respond that, even under the special master's finding, the Secretary did not meet her statutory burden of proving that TS was the cause of Michael's seizures. Citing Knudsen, they assert that the Court of Federal Claims improperly applied the "unity theory" of causation—i.e., accepting the only condition that explains all of the observed symptoms as the cause in fact. We rejected this theory as a basis of proof for alternative causation, holding also that "[t]he bare statistical fact that there are more reported cases of viral encephalopathies than there are reported cases of DTP encephalopathies is not evidence that in a particular case an encephalopathy following a DTP vaccination was in fact caused by a viral infection present in the child and not caused by the DTP vaccine." See Knudsen, 35 F.3d at 550. The Hanlons contend that the finding of causation here is similarly unjustified. We disagree.

Proof of the relationship between TS and Michael's seizures is much more than a "bare statistical fact." As noted, the Secretary presented evidence that the DPT vaccine does not cause afebrile seizures, that the cortical lesions or tubers in TS children do cause afebrile seizures, and expert opinion that TS, not the DPT vaccine, caused Michael's seizures. The special master did not conclude merely that TS was the most likely of several

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[2]We note, however, that TS does not necessarily preclude compensation in future cases: "No one expects a TS child to go into immediate status epilepticus (prolonged seizure) or even coma as his first sign of a seizure disorder. Where such an event occurs, the DPT vaccine is indeed the cause." Barnes, 1997 WL 620115, at *33.

possible causes. Rather, based on a "logical and legally probable" sequence of cause and effect, she determined that TS was the actual alternative cause of Michael's seizures. A reversal of this finding would improperly require proof of causation that is "medically or scientifically certain." Knudsen, 35 F.3d at 549.

We also reject the Hanlons' contention that the special master erred in allowing Dr. Gomez to testify because they had previously retained him as their expert witness. "We review such evidentiary rulings for abuse of discretion." NEC Corp. v. United States, 151 F.3d 1361, 1375 (Fed. Cir. 1998); see also Whitecotton v. Secretary of Health and Human Servs., 81 F.3d 1099, 1108 (Fed. Cir. 1996) ("[T]he permissible scope of the special master's inquiry is virtually unlimited. Congress desired the special masters to have very wide discretion with respect to the evidence they would consider and the weight to be assigned that evidence.").

It appears from the record that the Hanlons did not retain Dr. Gomez as an expert witness. He provided expert testimony in 1991 for the Hanlons' counsel in a different case. This does not mandate disqualification unless it is reasonable to conclude that Dr. Gomez possessed confidential information that would prejudice the Hanlons. See, e.g., Koch Ref. Co. v. Jennifer L. Boudreaux MV, 85 F.3d 1178, 1181 (5th Cir. 1996); Palmer v. Ozbek, 144 F.R.D. 66, 67 (D. Md. 1992). They present no evidence that warrants such a finding.

The special master asked for new testimony from Dr. Gomez, who had changed his opinion in light of recently published medical literature. See Barnes, 1997 WL 620115, at *22. Under section 300aa-12(d)(3)(B)(iii), a special master "may require the testimony of any person and the production of any documents as may be reasonable and necessary." Thus, it is not an abuse of discretion to consider new pertinent medical evidence that was not available at the time of the original petition. See McAllister v. Secretary of Health and Human Servs., 70 F.3d 1240, 1244 (Fed. Cir. 1995) ("The question whether to consider new evidence on . . . any . . . point previously decided is

committed to the special master . . . in the first instance."). The relevance of Dr. Gomez' testimony is clear and it was within the special master's discretion to call him as a witness.

Conclusion

Accordingly, the judgment of the Court of Federal Claims is affirmed.

AFFIRMED

APPENDIX K: ORDER OF THE UNITED STATES COURT OF APPEALS IN AND FOR THE FEDERAL CIRCUIT, DATED SEPTEMBER 8, 1999

184 F.3d 1380 (Mem.) (Fed. Cir. 1999)

United States Court of Appeals for the Federal Circuit
98-5168

MARC PLAVIN and TONI REISS,Parents and next friends of Rachel Leah Reiss-Plavin,

Petitioners-Appellants,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent-Appellee.

DECIDED: September 8, 1999

Before MAYER, Chief Judge, LOURIE, Circuit Judge, and BLACK, District Judge.* MAYER, Chief Judge.

The judgment of the United States Court of Federal Claims is affirmed for the reasons set forth in this court's opinion in Hanlon v. Secretary of Health and Human Services, 98-5120, filed today.

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* Honorable Bruce D. Black, District Judge, United States District Court for the District of New Mexico, sitting by designation.

APPENDIX L: ORDER OF THE CIRCUIT COURT OF APPEALS IN AND FOR THE FEDERAL CIRCUIT, DENYING REHEARING AND SUGGESTION OF REHEARING *EN BANC*, DATED OCTOBER 20, 1999

United States Court of Appeals for the Federal Circuit
98-5120

JOHN HANLON and RUTH ANN HANLON, Parents and next friends of Michael Hanlon,

Petitioners-Appellants,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent-Appellee.

ORDER

A combined petition for rehearing and suggestion for rehearing en banc having been filed by the APPELLANT, and the petition for rehearing having been referred to the panel that heard the appeal, and thereafter the suggestion for rehearing en banc having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the suggestion for rehearing en banc be, and the same hereby is, DECLINED.

The mandate of the court will issue on October 27, 1999.

FOR THE COURT,

Jan Horbaly
Clerk

Dated: October 20, 1999

cc: ROBERT T. MOXLEY
MARY HAMPTON MASON

HANLON V HHS, 98-5120
(CFC - 90-VV-1334)

Note: Pursuant to Fed. Cir. R. 47.6, this order is not citable as precedent. It is a public record.

APPENDIX M: JUDGMENT OF THE CIRCUIT COURT OF APPEALS IN AND FOR THE FEDERAL CIRCUIT, DATED SEPTEMBER 8, 1999

United States Court of Appeals for the Federal Circuit

98-5120

JOHN HANLON and RUTH ANN HANLON, Parents and next friends of Michael Hanlon,

Petitioners-Appellants,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent-Appellee.

Judgment

ON APPEAL from the UNITED STATES COURT OF FEDERAL CLAIMS

In CASE NO(S). 90-VV-1334

This CAUSE having been heard and considered, it is ORDER and ADJUDGED:

AFFIRMED

ENTERED BY ORDER OF THE COURT

DATED SEP - 8 1999

s/
Jan Horbaly, Clerk

ISSUED AS A MANDATE: OCTOBER 27, 1999

APPENDIX N: STATUTORY PROVISIONS OF VACCINE ACT, RELATING TO TRIAL JURISDICTION, ENTRY OF JUDGMENT, FINALITY, REVIEW, AND QUALIFICATIONS FOR ENTITLEMENT

Pertinent provisions of the National Childhood Vaccine Injury Compensation Act, 42 U.S.C. §§300aa-10 *et seq.*, provide as follows:

§ 300aa-11. Petitions for Compensation

(a) General rule. (1) A proceeding for compensation under the Program for a vaccine-related injury or death shall be initiated by service upon the Secretary and the filing of a petition . . . with the United States Court of Federal Claims. The clerk . . . shall immediately forward the filed petition to the chief special master for assignment to a special master.

* * *

(c) Petition content. A petition for compensation under the Program for a vaccine-related injury or death shall contain—

(1) . . . an affidavit, and supporting documentation, demonstrating that the person who suffered such injury or who died—

(A) received a vaccine set forth in the Vaccine injury Table . . .

* * *

(C) (i) sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with the vaccine . . . and the first symptom or manifestation . . . occurred within the time period after vaccine administration set forth in the Vaccine Injury Table . . .

§ 300aa-12. Court Jurisdiction

(a) General rule. The United States Court of Federal Claims and the United States Court of Federal Claims special masters shall, in accordance with this section, have jurisdiction over proceedings to determine if a petitioner under section 2111 [42 USCS § 300aa-11] is entitled to compensation under the Program and the amount of such compensation . . .

* * *

(c) United States Court of Federal Claims special masters.
(1) There is established within the United States Court of Federal Claims an office of special masters . . .

* * *

(d) Special Masters.

* * *

(3)(A) A special Master to whom a petition has been assigned shall issue a decision on such petition with respect to whether compensation is to be provided under the Program and the amount of such compensation. The decision of the special master shall—

(i) include findings of fact and conclusions of law, and
(ii) be issued as expeditiously as practicable . . .

The decision of the special master may be reviewed by the United States Court of Federal Claims in accordance with subsection (e).

* * *

(e) Action by the United States Court of Federal Claims. (1) Upon issuance of the special master's decision, the parties shall

have 30 days to file . . . a motion to have the court review the decision. . . . (2) Upon the filing of a motion under paragraph (1), the United States Court of Federal Claims shall have jurisdiction to undertake a review of the record of the proceedings and may thereafter—

> (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision.
>
> (B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or,
>
> (C) remand the petition to the special master for further action in accordance with the court's direction.

* * *

(3) In the absence of a motion under paragraph (1) respecting the special master's decision or if the United States Court of Federal Claims takes the action described in paragraph (2)(A) with respect to the special master's decision, the clerk of the United States Court of Federal Claims shall immediately enter judgment in accordance with the special master's decision.

(f) Appeals. The findings of fact and conclusions of law of the United States Court of Federal Claims on a petition shall be final determinations of the matters involved, except that the Secretary or any petitioner aggrieved . . . may obtain review of the judgment of the court in the United States Court of Appeals for the Federal Circuit upon petition[1] . . .

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[1] As required by Rule 14 (h), the provisions of § 300aa-12 are set forth herein to establish "the basis for federal jurisdiction in the court of first instance."

§ 300aa-13. Determination of eligibility and compensation

(a) General rule. (1) Compensation shall be awarded under the Program to a petitioner if the special master or court finds or the record as a whole—

(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 2111(c)(1)[42 USCS § 300aa-11(c)(1)], and

(B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.

(b) Matters to be considered. (1) In determining whether to award compensation to a petitioner under the Program, the special master or court shall consider, in addition to all other relevant medical and scientific evidence contained in the record—

(A) any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death, and

(B) the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.

Any such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the court. In evaluating the weight to be afforded to any such diagnosis, conclusion, judgment, test result, report, or summary, the special master or court shall consider the entire record and the course of the injury, disability, illness, or condition until the date of the judgment of the special master or court.

* * *

(c) "Record" defined. For purposes of this section, the term "record" means the record established by the special masters of the United States Claims Court in a proceeding on a petition . . .

§ 300aa-14. Vaccine Injury Table

(a) Initial table. The following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation . . . is to occur after vaccine administration for purposes of receiving compensation under the Program:

INITIAL VACCINE INJURY TABLE

I. DTP; P; DTP/Polio Combination; or Any Other Vaccine Containing Whole Cell Pertussis Bacteria, Extracted or Partial Cell Bacteria, or Specific Pertussis Antigen(s).

Illness, disability, injury, or condition covered:	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration:
* * *	
D. Residual seizure disorder in accordance with subsection (b)(2):	3 days